

**PATIENT MONITOR**  
**PM PRO-2**

**CONTROLLED COPY**

**MANUAL BOOK**

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# Chapter 1 Intended Use and Safety Guidance

The word “pediatrics” applied in this manual does not include neonates. Neonate is treated as a separate population for the patient monitor to conform to testing requirements.

## 1.1 Intended Use/Indications for Use

PM PRO-2 Patient Monitor (hereinafter called monitor) is intended to be used for monitoring, storing, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.

The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO<sub>2</sub>), pulse rate (PR), non-invasive blood pressure (NIBP), and invasive blood pressure (IBP), carbon dioxide (CO<sub>2</sub>) and cardiac output (C.O.).

The arrhythmia detection and ST Segment analysis are intended for adult only.

The monitor is additionally intended for use during patient transport inside and outside of the hospital environment.

The monitor is not intended for airplane, helicopter transport, home use and MRI environments.

## 1.2 Safety Guidance

Federal (U.S.) law restricts this device to sale by or on the order of a physician.

### **WARNING**

- 1 To ensure that the monitor works properly, please read the user manual and follow the steps before using the monitor.
- 2 Before using the device, the equipment, patient cable and electrodes etc. should be checked. Replacement shall be taken if there is any evident defect or signs of aging which may impair the safety or performance.
- 3 Medical technical equipment such as this monitor/monitoring system must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.
- 4 EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
- 5 Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.
- 6 Do not come into contact with the patient, table, or the monitor during defibrillation.

---

## **WARNING**

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- 7 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.
  - 8 The equipment can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT. The equipment can protect against the effects of the discharge of a defibrillator. Use only accessories approved by the manufacturer.
  - 9 Check both the positive and negative electrodes before the vehicle power is connected to the monitor.
  - 10 Under the vehicle condition, ensure the accessories are firmly connected to the monitor.
  - 11 Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
  - 12 Route all cables carefully to avoid possible entanglement, apnea, or electrical interference. For the device mounted over the patient, sufficient precautionary measures should be taken to prevent it from falling on the patient.
  - 13 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards. Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.
  - 14 The monitor is equipped with Wi-Fi to receive RF electromagnetic energy. Therefore, any other equipment complying with CISPR radiation requirements may also interfere with the wireless communication and make it interrupted.
  - 15 Only use patient cable and other accessories supplied by the manufacturer. The performance and electric shock protection cannot be guaranteed, and the patient may be injured otherwise. Prior to use, check if the casing of a disposable or sterilized accessory is intact. Do not use it if its casing is damaged.
  - 16 Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.
  - 17 Wireless LAN equipment contains an intentional RF radiator that has the potential of interfering with other medical equipment, including patient implanted devices. Be sure to perform the electromagnetic compatibility test before installation and any time new medical equipment is added to the Wireless LAN coverage area.
-

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## **WARNING**

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- 18 When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.
- 19 If several items of medical equipment are interconnected, pay attention to the sum of the leakage currents, otherwise it may cause shock hazard. Consult your service personnel.
- 20 If leakage or foul odor is detected, ensure that there's no fire around.
- 21 During monitoring, if the power supply is off and there is no battery for standby, the monitor will be off. The settings configured by the user can be stored, and settings not configured by user keep no change. That is, the last settings used will be recovered when the power is restored.
- 22 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Battery is hazardous waste. Do NOT dispose it together with house-hold garbage. At the end of its life hand the battery over to the applicable collection points for the recycling of waste batteries. Inappropriate disposals of waste may contaminate the environment. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.
- 23 The packaging is to be disposed of according to local or hospital's regulations; otherwise, it may cause environmental contamination. Place the packaging at the place which is inaccessible to children.
- 24 After defibrillation, the ECG display recovers within 10 seconds if the correct electrodes are used and applied based on the manufacturers' instructions.
- 25 Clinical decision making based on the output of the device is left to the discretion of the provider.
- 26 Do not touch the patient when you have contact to the monitor.
- 27 This equipment is not intended for home usage.
- 28 Do not service or maintain the monitor or any accessory which is in use with the patient.
- 29 Without use of data store function, all data measured (including trend data, review data, alarm events and so on) are cleared either when the monitor is turned off or when the monitor is powered down in the process of monitoring.
- 30 The appliance coupler or mains plug is used as isolation means from supply mains. Position the monitor in a location where the operator can easily access the disconnection device.
- 31 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
- 32 Portable multi-socket outlet or extension cord can't be connected to the system.
-

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## **WARNING**

- 33 Only items that have been specified as part of the system or specified as being compatible with the system can be connected to the system.
- 34 All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.
- 35 The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.
- 36 Connecting any accessory (such as external printer) or other device (such as the computer) to this monitor makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:
- Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and
  - Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.
- 37 Portable and mobile RF communications equipment can affect medical electrical equipment; refer to the recommended separation distances provided in this user manual.
- 38 Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.
- 39 The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you must check that normal operation is possible in the necessary configuration before you start monitoring patients.
- 40 Do not touch accessible parts of medical or non-medical electrical equipment in the patient environment and the patient simultaneously, such as USB connector, VGA connector or other signal input/output connectors.
- 41 **SHOCK HAZARD** - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.
- 42 **SHOCK HAZARD** - Don't connect electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.
- 43 Only recommended rechargeable batteries can be used for the monitor.
- 44 Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.
- 45 To protect the monitor from damage during defibrillation, for accurate measurement information and to protect against noise and other interference, use only accessories specified by the manufacturer.
-

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## **WARNING**

- 46 When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.
  - 47 No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
  - 48 The device is MR unsafe. It is not intended for use in an MRI environment.
  - 49 The monitor is suitable for use in the presence of electrosurgery. When the monitor is used with HF surgical equipment, user (doctor or nurse) should be cautious about patient safety.
  - 50 Make sure networking function is used in a secure network environment.
  - 51 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 

## **CAUTION**

- 1 Electromagnetic Interference - Ensure that the environment in which the patient monitor is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, microwaves, etc.
  - 2 Keep the environment clean. Avoid vibration. Keep it far away from corrosive medicine, dust area, high temperature and humid environment.
  - 3 Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.
  - 4 Avoid liquid splashing on the device.
  - 5 The device and reusable accessories may be sent back to the manufacturer for recycling or proper disposal after their useful lives.
  - 6 Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.
  - 7 Remove a battery whose life cycle has expired from the monitor immediately.
  - 8 To ensure patient safety, use only parts and accessories manufactured or recommended by the manufacturer.
  - 9 Before connecting the monitor to the DC power, make sure the voltage is consistent with the requirements indicated on the device label or in this user manual.
-

## **CAUTION**

- 10 Protect the device against mechanical damage resulting from falls, impacts, and vibration.
- 11 A ventilated environment is required for monitor installation. Do not block up the ventilation grille at the back of the device.
- 12 Touch screen is fragile, be gentle when using it and avoid excessive force that may cause damage to it.
- 13 Poor connection might be caused by frequently plugging and unplugging the power cord. Check the power cord regularly and replace it in time.

## **NOTE:**

- 1 Position the device in a location where the operator can easily see the screen and access the operating controls.
- 2 The monitor can only be used on one patient at a time.
- 3 If the monitor gets damp or liquid pours on the monitor, please contact the service personnel of the manufacturer.
- 4 This monitor is not a device for treatment purposes.
- 5 The pictures and interfaces in this manual are for reference only.
- 6 Regular preventive maintenance should be carried out every two years. You are responsible for any requirements specific to your country.
- 7 When there's measurement beyond range, invalid measurement or no measurement value, it will display -?-.
- 8 The materials with which the patient or any other person can come into contact conform to the standard of EN ISO 10993-1: 2009.
- 9 In normal use, the operator shall stand in front of the monitor.

### **1.2.1 Protecting Personal Information**

Protecting personal health information is a major component of security strategy. To protect the personal information and ensure the proper device performance, the user should take necessary precautions in accordance with local laws and regulations and institution's policies. The manufacturer recommends health care organizations or medical institutions to implement a comprehensive and multifaceted strategy to protect the information and systems from internal and external security threats.

To ensure the patients' safety and protect their personal health information, the user should implement practices or measures that include:

1. Physical safeguards - physical safety measures to ensure that unauthorized personnel do not have access to the monitor.
2. Operational safeguards - safety measures during operation.
3. Administrative safeguards - safety measures in management.

4. Technical safeguards - safety measures in technical field.

**CAUTION**

- 1 The access/operation of the monitor is restricted to authorized personnel only. Assign only staff with a specific role the right to use the monitor.
- 2 Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e. cannot remove without tools).
- 3 Ensure that the data are deleted after the patient is discharged (Refer to Section *Deleting Data Stored in the Storage Device*).
- 4 Ensure that the monitor is connected only to the device authorized/approved by the manufacturer. Users should operate all deployed and supported monitors within the manufacturer's authorized specifications, including the manufacturer's approved software, software configuration, security configuration, etc.
- 5 Protect all the passwords to prevent unauthorized changes. Only the manufacturer's service personnel are allowed to modify the **Factory Maintain** settings.
- 6 Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.
- 7 Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It's recommended to use Windows defender firewall or any other firewall that can defend against DoS and DDoS attacks, and keep it up to date.
- 8 DoS and DDoS protection of the router or switch must be turned on for defending against attacks.
- 9 To avoid malicious tampering and theft of data transmitted by the network, it is recommended to switch on the encryption function. After the encryption function is turned on (it is set to on by default), the monitor will authenticate the accessed MFM-CMS and Gateway devices and encrypt the transmitted data to ensure the security.
- 10 When building the networking environment: 1) If a wireless router is used, please turn on the MAC address filtering function of the wireless router and add the MAC address of the monitor to the rule list. The wireless router only allows devices in the rule list to access the wireless network. 2) It is suggested to build a VLAN, assign the LAN ports where the approved switch port, monitor and MFM-CMS are into the same VLAN, and isolate it from other VLANs.
- 11 When the monitor is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the monitor (Refer to Section *Deleting Data Stored in the Storage Device*).
- 12 Please protect the privacy for the information and the data displayed on the screen, and for the information and the data stored in the monitor.

#### **NOTE:**

Log files generated by the monitor are used for system troubleshooting and do not contain protected medical data.

#### **1.2.2 Security**

For more security operations, select **Menu > User Maintain** and input user maintain password > **Security**. In this menu:

- Select **Modify User Password**, the user can change the password according to the prompts. For safety considerations, change the password periodically, and a combination of words and numbers is recommended. If **Old Password** is forgotten, contact Service personal for help.
- Click **Firewall Rules** to check rule details.
- Set **Auto Login** to On/Off.

When it is set to **On**, the monitor can enter the normal working interface after start-up; when it is set to **Off**, after start-up, the screen of the monitor is locked, clicking the screen, a password window will be displayed, and the monitor can enter the normal working interface until correct password is input. Default setting is **On**.

- Select the minutes in **User login Timeout**. If there are no any operations to the monitor for XX minutes (**5, 15, 30, 60** and **Never**), the screen will enter into the screensaver status. User Maintain password should be correctly input before user operates the monitor again. The selection **Never** means the monitor will never enter into screensaver status and still in the normal working status. Default setting is **Never**.
- Set **Firewall** to **On** to protect against hacker attacking.
- Set **Packets Limit** value for traffic monitoring. If the data traffic per minute exceeds the preset threshold, the monitor will trigger the alarm “**Network traffic anomaly**” to remind the user, and at the same time, the network will disconnect for 5 minutes. After 5 minutes, the network will be re-connected and alarm disappears.
- Set **CMS/Gateway Encryption** to **Off**, **TLS** or **AES** (default) when user connects the monitor with network server (MFM-CMS or gateway).
- Set **HL7** to **On/Off**. The monitor supports HL7 protocol to upload data. To avoid hacker attacking, setting **HL7** to **Off** is normally recommended.

User can also set **HL7 IP** address of client-side in **User Maintain > Network Maintain**.

- Set **HL7 Encryption** method to **Off** or **TLS** (default).
- Click **Import Certificate** to install/upgrade the **Certificate** via USB flash drive. The certificate issued by Certificate Authority (CA) is recommended and self-signed certificate should be avoided. For detailed steps of importing certificates, please refers to service manual.

#### **NOTE:**

- 1 When the monitor is turned on for the first time or after upgrading software, modify the **User Maintain** password according to the prompts. The default initial **User**

Maintain password is **ABC**. After modifying the password, please keep it safe.

- 2 When any password is input incorrectly for more than 5 times, the monitor will display the information: **More than five consecutive password errors**, after that, the input times of wrong password will be recorded in the monitor log.

### 1.3 Explanation of Symbols on the Monitor

1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
3		Warning (Background: Yellow; Symbol & outline: black)
4		Caution
5		Operating instructions
6		Refer to User Manual (Background: Blue; Symbol: White)
7		Direct Current
8		Battery check
9		Chargeable battery
10		On/Off indicator
11		Power Supply switch
12		Serial number
13		USB (Universal Serial Bus) Connection
14		Bell cancel – AUDIO OFF
15		NIBP measurement

16		Menu
17		CE marking
18		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
19		Date of manufacture
20		MANUFACTURER
21	P/N	Part Number
22		General symbol for recovery/recyclable
23		Disposal method
24		Anti-electroshock type: Class II equipment
25	IP44	Ingress Protection: IP44 (protected against splashing water and solid foreign objects ≥ 1.0 mm diameter)
26	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
27		Gas inlet
28		Gas outlet (evac)
29		Non-ionizing electromagnetic radiation

30		MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment
31		This way up
32		Fragile, handle with care
33		Keep dry
34		Stacking limit by number
35		Handle with care
36		Do not step on

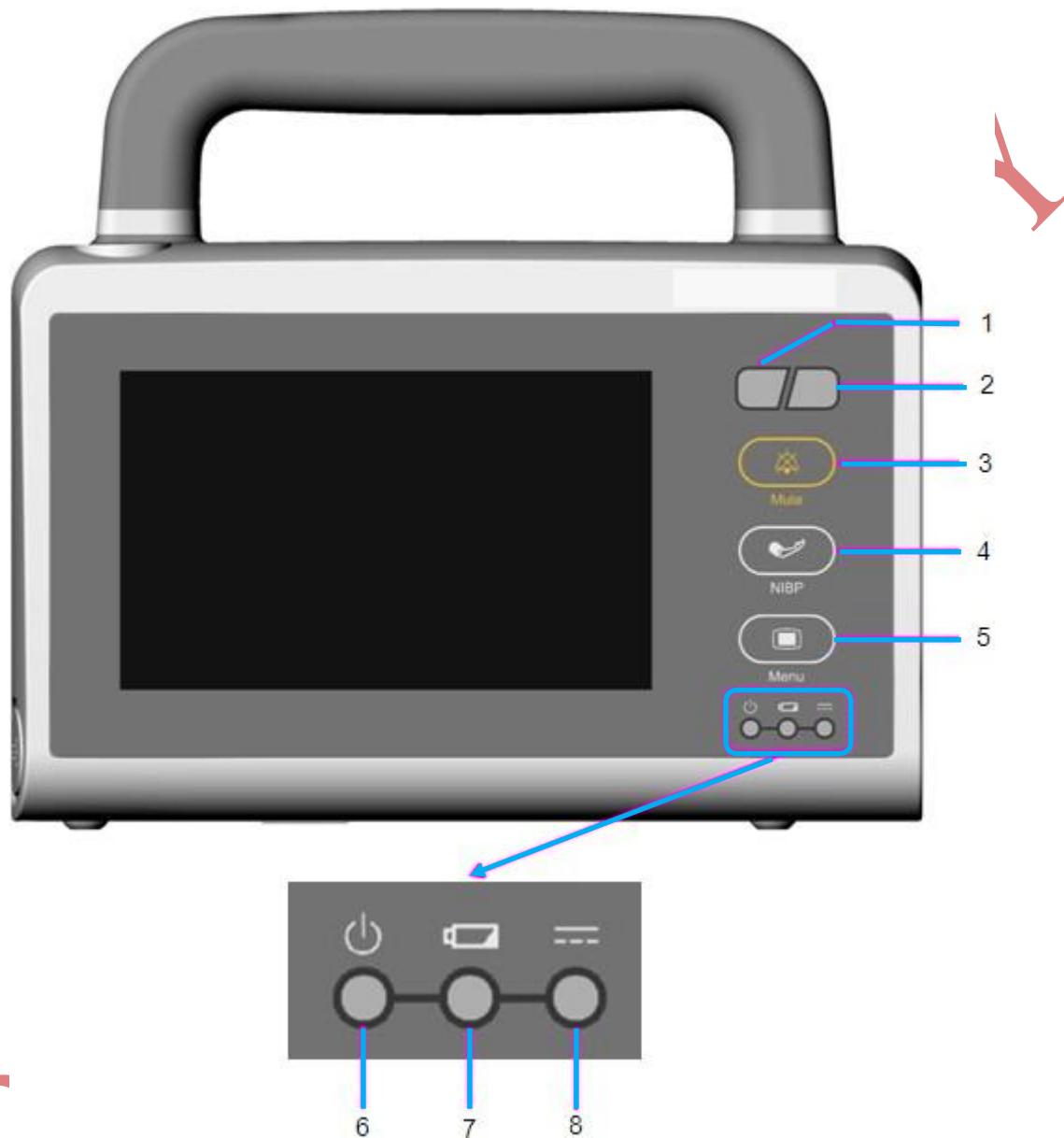
**NOTE:**

The user manual is printed in black and white.

## Chapter 2 Overview

### 2.1 Main Unit

#### Front View



1 Technical alarm indicator

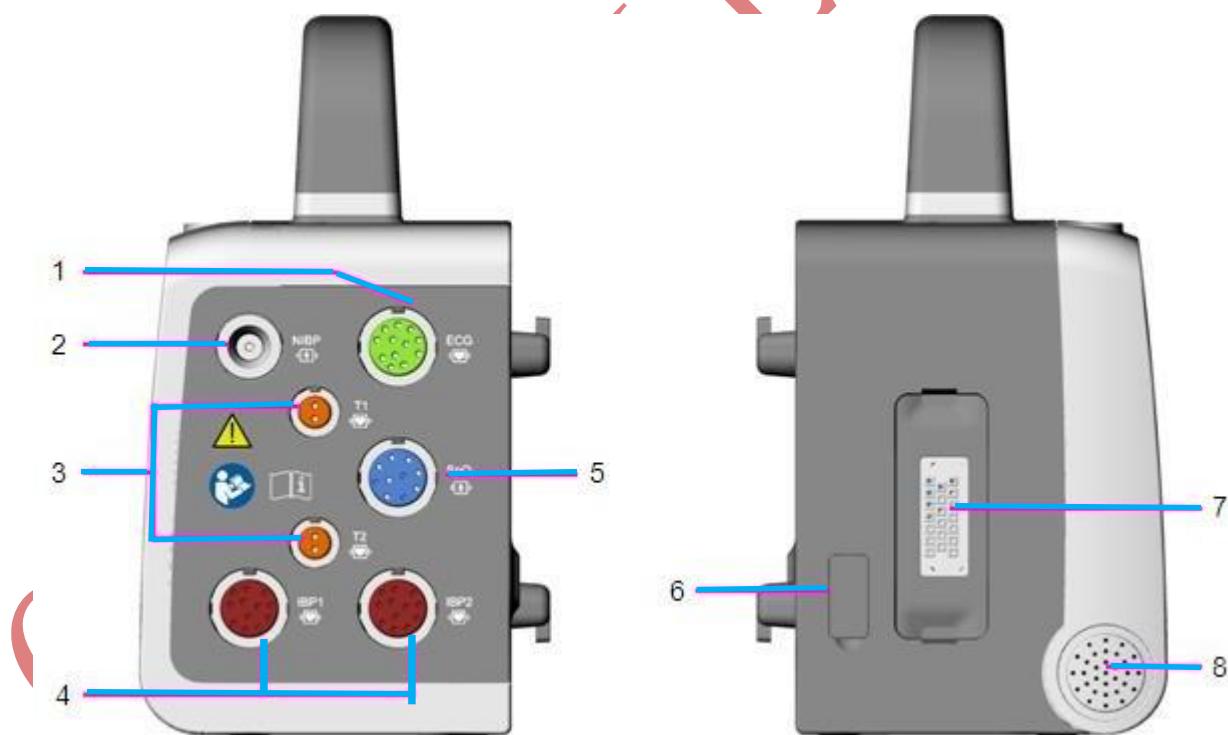
When a technical alarm occurs, the indicator lights on or flashes with different frequencies and colors reflecting the alarm level.

2 Physiological alarm indicator

When a physiological alarm occurs, the indicator lights on or flashes with different frequencies and colors reflecting the alarm level.

3	Mute	Press it to suspend the output of all audible alarm signals. Upon the configuration, pressing this button to pause or turn off the audio alarm. Further information can be found in the Section <i>Audio Alarm Paused</i> and Section <i>Audio Alarm Off</i> .
4	Start/stop NIBP measurement	Press it to start or stop blood pressure measurement.
5	Menu	Pressing it will enter the shortcut widget, where you can find the shortcut keys.
6	On/Off indicator	Green when monitor is on.
7	Battery indicator	Refer to the Section <i>Battery Power Indicator</i> for details.
8	DC power indicator	Green when monitor is powered from an external power source.

## Side View




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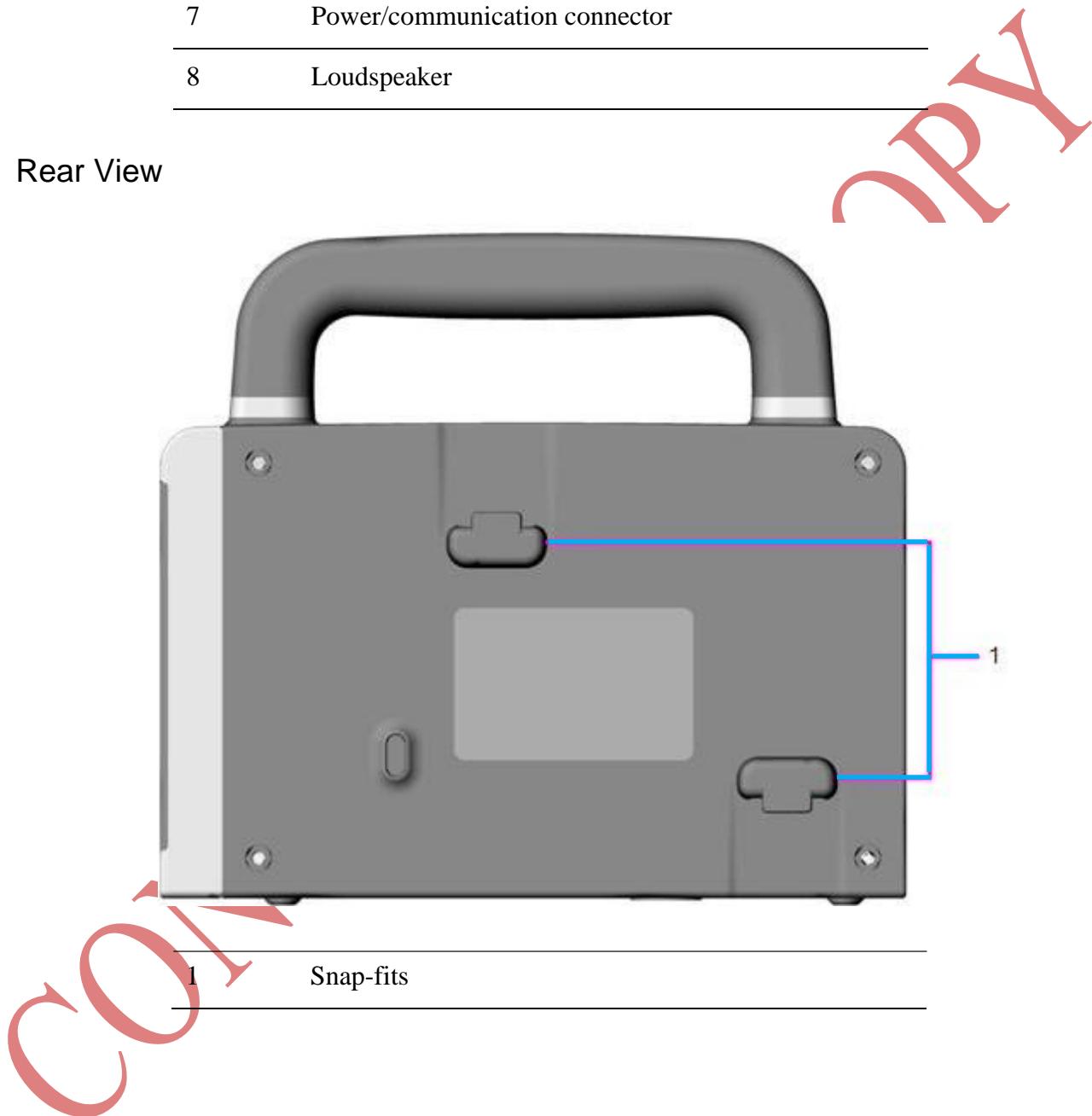
1 ECG cable connector

---

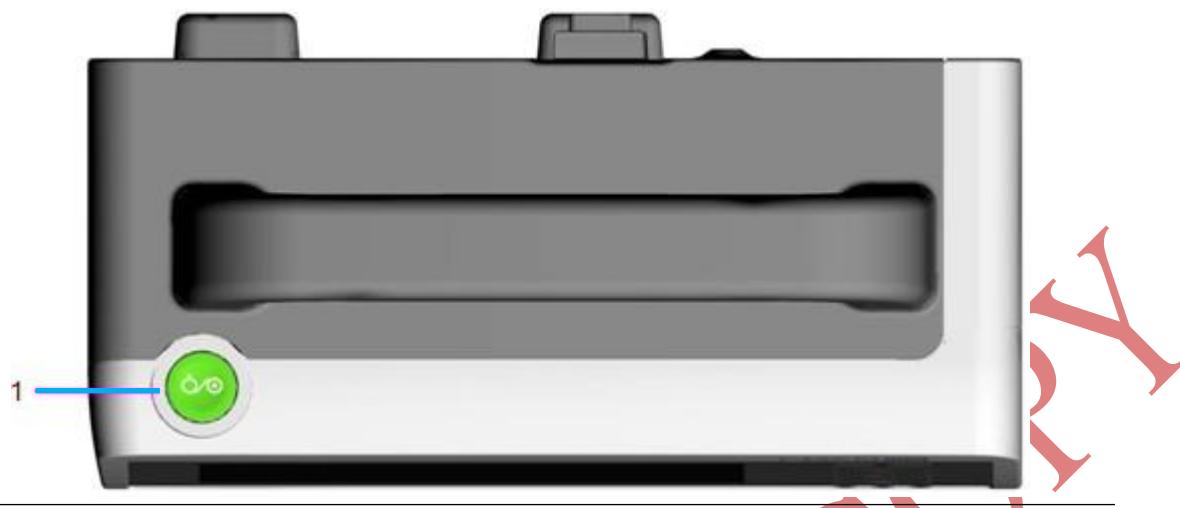
2 NIBP cuff connector

- 
- 3 TEMP probe connectors
  - 4 IBP transducer connectors
  - 5 SpO<sub>2</sub> sensor connector
  - 6 USB connector
  - 7 Power/communication connector
  - 8 Loudspeaker
- 

Rear View



## Top View



1 Power supply switch

Press it to turn the monitor on, or press the key for 3 seconds to turn the monitor off when the monitor is on.

## Bottom View



1 Battery cover

2 Battery compartment latch

3 Heat sink

## 2.2 EFM-Extension Function Module (Optional)

The EFM provides CO<sub>2</sub> parameter. By connecting it to the monitor you can get the CO<sub>2</sub> parameter, if present. Plug the EFM in the interface on the left side of the monitor, and it is connected with the monitor as shown below:



- 
- 4      Gas outlet (Sidestream)
  - 5      Button – Press it to help release the EFM.
  - 6      Snap-fits
- 

## Installing the EFM

Plug the EFM in the interface on the left side of the monitor. Mate the catches of the module with the snap-fits on the rear of the monitor, and fasten the module until the snap-fits click into place. To separate the module from the monitor, press the button on the bottom, and slide it out aligning the interface direction.



When the EFM is connected to the monitor, it shares the monitor's settings and power. Trend data and measurement settings in the EFM are stored in the monitor.

---

### **WARNING**

---

The EFM can only function when it is connected to the monitor.

---

# Chapter 3 Installation

## NOTE:

The monitor settings must be configured by the authorized hospital personnel.

## 3.1 Initial Inspection

Before unpacking, check the packaging and ensure that there are no signs of mishandling or damage. If the shipping cartons are damaged, contact the carrier for compensation and package them again.

Open the package carefully and remove the monitor and accessories. Check that the contents are complete and that the correct options and accessories have been delivered.

If you have any question, please contact your local supplier.

## 3.2 Mounting the Monitor

Place the monitor on a flat, level surface, mount it on a wall mounting system, hung on the bed rail, or carry it by strap.

## 3.3 Connecting the Power Supply

Before connecting the monitor to the mains, ensure the power adapter conforms to the following specifications:

- AC power adapter: input 100 V-240 Vac, 50 Hz/60 Hz, output 15 V $\pm$ 5% dc
- DC power adapter: input 12.4 V - 15.1 Vdc or 24.8 V - 30.3 Vdc, 1.6 A max, output 15 Vdc, 1 A max

Connect the power cord provided with the monitor. Connect the power cord to connector of the monitor. Connect the other end of the power cord to a grounded power outlet.

## NOTE:

- 1 Connect the power cable to the socket specialized for hospital use.
- 2 Only use the power cable supplied by the manufacturer.

### 3.3.1 Host Monitor as Power Source

When connected to the PM PRO-1 patient monitor, via the cable or when directly attached to the host monitor, the monitor obtains its power from the host monitor, including that needed for battery charging.

## NOTE:

The monitor will charge its battery only when attached to a host monitor being connected to the mains.

### 3.4 Checking the Monitor

Make sure there is no damage on the measurement accessories and cables. Then turn on the monitor, check whether the monitor can start normally. Make sure all alarm lamps light up and the alarm sound is heard when turning on the monitor. Please refer to chapter *Testing Alarms*.

#### **WARNING**

If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact Customer Service Center immediately.

#### **NOTE:**

- 1 Check all the functions of the monitor and make sure that the monitor is in good status.
- 2 If rechargeable battery is provided, charge it each time before using the device to ensure adequate power.
- 3 After long-time continuous running, please restart the monitor to ensure the monitor's steady performance and long lifespan.

### 3.5 Setting Date and Time

To set the date and time:

1. Press the hardkey Menu on the front panel to enter the shortcut widget.
2. Select **Menu > Maintenance > User Maintain > Date/Time Setup**.
3. Adjust the **Date Format** and **Clock Format** based on the user's habit.
4. Set the correct time of year, month, day, hour, min and sec.

If the monitor is connected to a host monitor, the date and time are automatically synchronized with the host monitor.

#### **NOTE:**

- 1 If the system is not used for a longer period of time, its system time may be inaccurate. In this case, readjust the system time after powering on.
- 2 If the system time cannot be saved and resumes the default value after restart, contact the service department of the manufacturer to replace the button cell in mainboard.
- 3 The default clock format is 24 hours. When **Clock Format** is set to **12 Hours**, please select AM or PM according to actual situation.

### 3.6 Handing Over the Monitor

If you are handing over the monitor to the end-users directly after configuration, make sure that it is in normal working status and let user know the status.

The users must be adequately trained to use the monitor before monitoring a patient. To achieve this, they should have access to, and read, the following documentation delivered with the monitor:

- User Manual (this book) - for full operating instructions.
- Quick Reference Card - for quick reminders during use.

### 3.7 FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

#### **NOTE:**

The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate this equipment.

### 3.8 FCC RF Radiation Exposure Statement

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

## Chapter 4 Basic Operation

This user manual is based on the maximum configuration and therefore your monitor may not have all of the functions and options described in the manual. Also, illustrations in this manual serve as examples only and do not necessarily reflect the setup on your monitor. The content displayed on your monitor depends on the way it has been tailored for your hospital.

You may frequently use the following functions:

- ◆ ECG monitoring (Refer to Chapter *Monitoring ECG* for details)
- ◆ SpO<sub>2</sub> monitoring (Refer to Chapter *Monitoring SpO<sub>2</sub>* for details)
- ◆ PR monitoring (Refer to Chapter *Monitoring PR* for details)
- ◆ TEMP monitoring (Refer to Chapter *Monitoring TEMP* for details)
- ◆ NIBP monitoring (Refer to Chapter *Monitoring NIBP* for details)
- ◆ Alarm (Refer to Chapter *Alarms* for details)

### 4.1 Introducing the Monitor

The monitor can be used in two ways:

- As an independent monitor.
- As a multi-measurement module for PM PRO-1 patient monitor (also called the host monitor in this manual).

Combining its two roles, the monitor helps eliminate data gaps, which is particularly suitable for transport environments. When the monitor is disconnected from the original PM PRO-1 patient monitor, it continues to monitor the patient as an independent monitor running on battery power, eliminating the need for a separate transport monitor. When the monitor is connected to a new PM PRO-1 patient monitor, it can share its patient data and acts its role as multi-measurement module, without losing a moment of critical monitoring information.

#### 4.1.1 Serving as an Independent Monitor

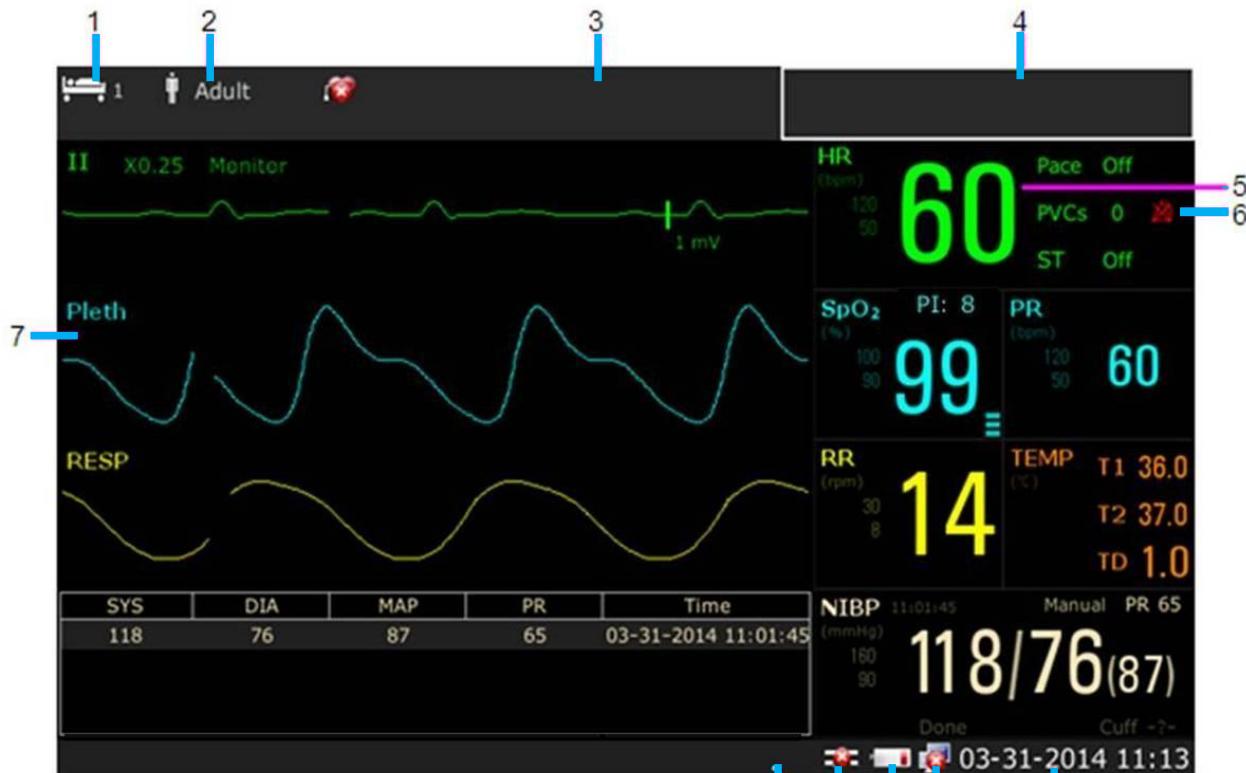
The monitor can operate as fully independent monitor. As an independent monitor, the monitor can simultaneously monitor, store, review several parameters data. It can transfer patient data to PM PRO-1 patient monitor as transport monitor. As a highly portable monitor, its compact design makes it particularly suited to transport environments.

#### 4.1.2 Serving as a Multi-Measurement Module

The monitor can be coupled with PM PRO-1 patient monitor, where it acts as a multi-measurement module, providing the measurements, trends, and patient information for PM PRO-1 patient monitor. You can connect the monitor to PM PRO-1 patient monitor by plugging it into the host monitor directly or via the cable. When connected to a host monitor, the host monitor controls the connected monitor, including all alarm functionality. No alarms are available on the monitor, and the monitor takes power from the host monitor. Different from other multi-measurement modules, the monitor can store its measurement data and settings. Refer to Section *Using the Monitor with a Host Monitor* for more information.

## 4.2 Operating and Navigating

Everything you need to operate the monitor is contained on its screen. Almost every element on the screen is interactive. Screen elements include measurement numerics, waveforms, screen keys, information fields, alarms fields and menus. The configurability of the monitor means that often you can access the same element in different ways. The User Manual always describes how to access items via an on-screen menu. You may use whichever way you find most convenient.



- |   |                                 |    |                            |
|---|---------------------------------|----|----------------------------|
| 1 | Bed number                      | 7  | Parameter waveform         |
| 2 | Patient type                    | 8  | Wi-Fi                      |
| 3 | Technical alarm status area     | 9  | Symbol for DC power supply |
| 4 | Physiological alarm status area | 10 | Symbol for battery status  |
| 5 | Measurement value               | 11 | Symbol for networking      |
| 6 | Symbol for alarm off            | 12 | Date and time              |

### 4.2.1 Using Keys

If the key sound is enabled, the monitor gives a normal key sound when the operation is valid.

#### 4.2.1.1 Main Setup Menu

The User Manual generally describes entry to a measurement's setup menu via the main setup menu, as this route is always available and is not subject to configuration dependencies. You can get to all setup windows from the main setup menu. You enter the main setup menu by pressing

the hardkey **Menu** on the front panel, then selecting the shortcut key



#### 4.2.1.2 Hardkeys

Hardkeys are the physical keys on the front panel of the monitor. The monitor has the following hardkeys: Mute, NIBP, and Menu. Refer to the illustration in Section *Main Unit* for more information.



#### 4.2.1.3 Shortcut Keys

Pressing the hardkey Menu will enter the shortcut widget, where you can find the shortcut keys.

A shortcut key is a configurable graphical key, which gives you fast access to functions. The selection of shortcut keys available on your monitor depends on your monitor configuration and on the options purchased. You can select the shortcut keys those need to be displayed on the shortcut widget screen through **Menu > Maintenance > User Maintain > Shortcut Setup**. You can adjust the shortcut key sequence as need.



Reset the alarm



Enter the main setup menu –  
you can get to all setup  
windows using this key



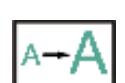
Switch to the standard screen



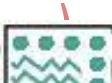
Switch to the OxyCRG screen



Switch to the trend screen



Switch to the large font screen



Switch to the vital screen



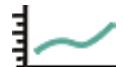
Transfer the patient



Admit a patient



Set the module switch

	Change the beat volume		Change the key volume
	Review the trend graph		Adjust the screen brightness
	Review the trend table		Zero the IBP sensor
	Review the alarm event		Alarm setup
	Access the NIBP review		Access the ARR review
	Perform a 12-lead analysis		Exit from 12-lead analysis
	Access the 12-lead review		Enter standby mode
	Lock the touch screen		Enter night mode
	Enter MEWS interface		Enter privacy mode
	Audio alarm paused/off		Start or stop NIBP measurement

#### 4.2.1.4 Pop-up Keys

Pop-up keys are task-related graphical keys that appear automatically on the screen when required. For example, the confirmation pop-up key appears only when you need to confirm a change.

### 4.3 Operating Mode

#### 4.3.1 Demo Mode

To change the operating mode into the demo mode, please refer to the following procedure:

Select **Menu > Common Function**, then choose **Demo Mode** from the popup interface and input password **3045**.

To exit **Demo Mode**, select **Menu > Common Function > Demo Mode**.

**WARNING**

Demo Mode is for demonstration purposes only. You must not change into Demo Mode during monitoring. In Demo Mode, all stored trend information is deleted from the monitor's memory.

### 4.3.2 Standby Mode

To enter into standby mode, select **Menu > Common Function > Standby**, or press the shortcut key  on the shortcut widget screen directly, the monitor enters into standby mode after user's confirmation.

In standby mode:

1. The monitor stops monitoring patients and stores previous monitoring data.
2. The monitor won't respond to all alarms and prompts, except Battery Low alarm.
3. Audio alarm paused status discontinues. Audio alarm off, alarm off, alarm reset and alarm latch status are not influenced.
4. MFM-CMS won't update monitoring data, and will display monitor's standby mode. If network is disconnected, monitor will make request for connection.
5. The connected host monitor enters into standby mode simultaneously.

The monitor exits standby mode in any of the conditions:

1. The user clicks anywhere on the screen or presses any key (except Power ON/OFF key).
2. Battery Low alarm occurs.
3. When PM PRO-2 is mounted to the host monitor.
4. The monitor is connected to MFM-CMS.

After exiting standby mode, the monitor resumes monitoring, including parameter monitoring, storage and alarm.

**NOTE:**

1. When the monitor is in transfer status, do not use standby mode, otherwise, device/data transferring might be affected.
2. The monitor is unable to enter into standby mode when exporting data.

### 4.3.3 Night Mode

To switch to night mode, you may:

- Select the shortcut key  on the shortcut widget screen, or
- Select **Menu > Common Function > Night Mode**.

**NOTE:**

In night mode, the sound of key, heart beat and pulse is muted; the alarm volume and screen brightness are down to their minimum; the settings including key volume, beat volume, PR volume, alarm volume and screen brightness are unavailable.

#### 4.3.4 Privacy Mode

Only if the monitor is connected and admitted by MFM-CMS, the privacy mode can be activated. To enter into privacy mode, you can select **Menu > Maintenance > User Maintain > Shortcut**

**Setup > Privacy Mode** (it is defaulted to be off). Press the shortcut key  on the shortcut widget screen n, the monitor enters into privacy mode after user's confirmation.

In privacy mode:

1. The screen displays message: **Privacy mode and Patient is in monitoring without audio alarm and alarm indicator lighting. Please click screen or hard key to exit.**
2. Monitoring data, alarm information, stored data and monitor status are transmitted to MFM-CMS.
3. Audio alarm paused status discontinues. Audio alarm off, alarm off, alarm reset and alarm latch status are not influenced.
4. The connected host monitor enters into privacy mode simultaneously.

The monitor exits privacy mode in any of the conditions:

1. The user clicks anywhere on the screen or presses any key (except Power ON/OFF key).
2. Battery Low alarm occurs.
3. The monitor is disconnected with MFM-CMS.
4. When PM PRO-2 is mounted to the host monitor.

**NOTE:**

1. When the monitor is in transfer status, do not use privacy mode, otherwise, device/data transferring might be affected.
2. The monitor is unable to enter into privacy mode when exporting data.

#### 4.3.5 NFC Mode

NFC mode means HR physiological alarms can't be turned off. To configure NFC mode, select **Menu > Maintenance > User Maintain > Alarm Setup** and choose **NFC Mode** which can be set to **On** or **Off**. NFC mode is off by default.

In NFC mode:

1. The HR physiological alarms are always on and can't be set to off by the user.
2. The user can't turn off the audio alarm permanently.
3. The audio alarm off status will be finished and the monitor enters normal alarm response

- status. **Pause Time** will automatically switch to **120 s**, which can be set to **60 s**, **120 s**, or **180 s** manually.
4. The audio alarm paused status is not affected by entering NFC mode.
  5. Symbol **NFC** is displayed in the HR parameter area.
  6. Monitoring data, alarm information, stored data and monitor status are transmitted to MFM-CMS.

**NOTE:**

NFC mode and standby mode can't coexist. When the monitor enters the standby mode, the NFC mode will automatically pause. After exiting the standby mode, the monitor will automatically resume the NFC mode.

After exiting NFC mode:

1. The HR physiological alarms are still on and can be set to off by the user.
2. **Pause Time** keeps no change and the user can set it to **Permanent**.
3. Symbol **NFC** gets disappeared.

## 4.4 Changing Monitor Settings

### 4.4.1 Adjusting Screen Brightness

To change the screen brightness, please:

1. Select  on the shortcut widget screen, or.
2. Select **Menu > Common Function > Brightness**, and select the appropriate setting for the screen brightness. **10** is the brightest, **1** is the least bright.

Your monitor may be configured with lower brightness in standby mode and also for transport to conserve battery power.

### 4.4.2 Changing Date and Time

To change the date and time, please refer to Section *Setting Date and Time*.

---

**WARNING**

---

A change in date and time will influence the storage of trend data.

## 4.5 Adjusting Volume

### 4.5.1 Adjusting Key Volume

The key volume is the volume you hear when you select any field on the monitor screen. To adjust the key volume, please:

1. Select  on the shortcut widget screen, or.

2. Select **Menu > System Setup > Key Volume**, then select the appropriate setting for the key volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the key volume will be off.

#### 4.5.2 Adjusting Alarm Volume

To change the alarm volume, please

1. Select  on the shortcut widget screen, or
2. Select **Menu > Alarm Setup** and select the desired setting for the **Alarm Volume** item: five bars represent the maximum volume and one bar represents the minimum volume.

#### 4.5.3 Adjusting Beat Volume

Beat volume is from HR or PR, depending on your setting of the beat source. To change the beat volume:

1. Select  on the shortcut widget screen, or
2. Select **ECG Setup > Beat Volume**, then select the appropriate setting for the beat volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the beat volume will be off. Beat frequency has positive correlation with measurement value.

### 4.6 Checking Your Monitor Version

To check the monitor version, please select **Menu > Common Function > About** to check the monitor software revision.

### 4.7 Networked Monitoring

Your monitor can be connected to the Wi-Fi. If the monitor is networked, a network symbol is displayed on the screen.

For more information about Wi-Fi, please refer to Section *Wi-Fi*.

**NOTE:**

When selecting dynamic IP mode, please check the IP address from MFM-CMS.

### 4.8 Setting Languages

To change the language, please:

1. Select **Menu > Maintenance > User Maintain**, then type the correct password into the displayed interface.
2. Select the **Language** option on the popup interface to open the language list.
3. Select the desired language from the list. To make the change valid, please restart the monitor.

## 4.9 Setting Keyboard Languages

The monitor is equipped with Chinese keyboard, English keyboard and Russian keyboard. To change the keyboard language, select **Menu > Maintenance > User Maintain > Keyboard Language**, then select the desired language from the list.

### NOTE:

The keyboard language will restore to the default language when the system language changes. User can change the keyboard language as needed.

## 4.10 Disabling the Touch Screen

The user can disable touch screen operation by selecting the **Lock Screen** shortcut key . A message of **Screen Locked** is displayed on the screen if the touch screen is disabled. To enable the

touch screen operation, long press on the symbol  in the center of the screen.

### NOTE:

When the monitor is in transfer status, ensure the touch screen is locked.

## 4.11 Calibrating Screens

To calibrate the screen, please refer to the following steps:

1. Select **Menu > Maintenance > User Maintain**, input the user password, and select **TouchScr Calibration** on the **User Maintain** menu. User can also enter into calibration interface through pressing shortcut key F9 in connected keyboard.
2. The symbol  appears on the screen.
3. Click on the central point of the symbol .

When PM PRO-2 is connected to PM PRO-1 monitor, and they are turned on (PM PRO-1 monitor is not in Demo mode), user can select **Menu > Maintenance > User Maintain** in PM PRO-1 monitor, input the user password, and select **TouchScr Calibration > Subordinate Monitor**, then operate as above Step 2 and Step 3 in PM PRO-2.

### NOTE:

- 1 If calibration file is lost or damaged, the monitor will automatically enter into screen calibration interface.
- 2 In the screen calibration interface, the screen turns gray and no measurement data can be displayed.
- 3 Please calibrate the screen when the monitor is turned on for the first time. Due to the change of ambient temperature, the touch screen may not be sensitive after running for a period of time, please calibrate the screen to ensure the monitor's proper operation.

## 4.12 Power on/Power off Behavior

The general rules determining the behavior of the monitor when connected to, or disconnected from power are as follows:

- When DC mains power is lost, a battery powered monitor continues to run without interruption on battery power.
- The monitor switches on automatically when connected to a running host monitor.
- When a battery powered monitor is disconnected from a running host monitor, it continues to run without interruption on battery power.
- When the host monitor switches on, the monitor on connection switches on simultaneously.
- When the running host monitor switches off, the monitor on connection switches off simultaneously.
- When the monitor on connection switches off, the running host monitor remains power-on.

## 4.13 Using the Monitor with a Host Monitor

When you connect the monitor to a host monitor, an integrated system is formed for monitoring a single patient. The following general observations apply to such a system:

- The host monitor is the “master” of the system, and only via the host monitor you have full control over all the system’s operation.
- General settings from the host monitor are applied to the monitor on connection.
- No audible alarms are available on the monitor when connected to a host monitor. The only visual alarm indication is provided by the alarm indicators which are controlled by the host monitor. Alarms become active again as soon as the monitor is disconnected from the host monitor.
- The date and time on the monitor is synchronized with that of the host monitor.

**NOTE:**

Inconsistent time might occur when the monitor is using with the host monitor for a period of time. Typically, there’s a maximum time difference of 10 seconds in three days.

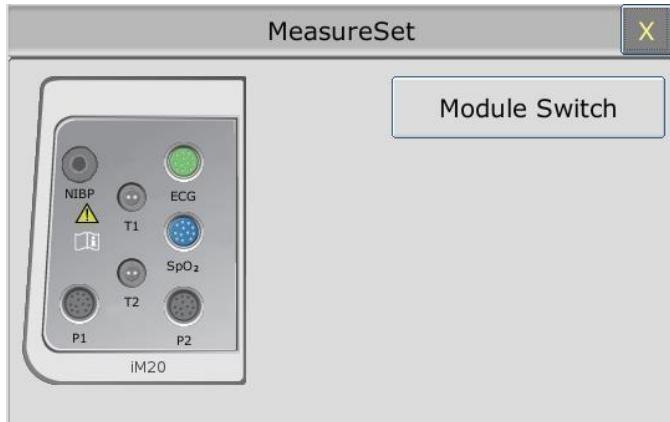
### 4.13.1 Setting Parameters

When you connect the monitor to PM PRO-1 patient monitor, the monitor acts as a multi-measurement module and you may find module conflicts or IBP label conflicts. You can set the parameters on the PM PRO-1 patient monitor as follows.

#### 4.13.1.1 Accessing the Parameter Menu



Select **MeasureSet** on the bottom of the screen to enter the **MeasureSet** menu as shown below. The display on your host monitor may be configured to look slightly different depending on the modules mounted.



The color in which a measurement connector appears matches the status of the measurement parameter.



Colored: indicates the module is activated.



Grey: indicates the module is deactivated.



Colored with a “!” appearing: indicates a module conflict.



For IBP connectors, with a circle-slash symbol appearing: indicates an IBP module conflict.



For IBP connectors in the module: indicates this module is not configured with an IBP module.

#### 4.13.1.2 Activating / Deactivating a Parameter Measurement

For different measurement parameters, approaches to parameter activation / deactivation may vary a little. Take the parameters ECG and NIBP in the module for example:

- ◆ To activate / deactivate the ECG measurement, select the ECG connector in the module on the **MeasureSet** menu, and set the ECG measurement to on or off on the pop-up submenu.
- ◆ To activate / deactivate the NIBP measurement, select the NIBP connector in the module on the **MeasureSet** menu, and the NIBP measurement will directly be activated / deactivated.

#### 4.13.1.3 Resolving Module Conflicts

This host monitor supports a maximum of eight channels of IBP measurement. Both the PM PRO-2 module and each V-IBP module provide two channels of IBP measurement. A maximum of four V-IBP modules can be used simultaneously if the PM PRO-2 module is not used, while three if the PM PRO-2 module is used. If eight channels of IBP measurement are loaded, another IBP module's plugging in will trigger an IBP module conflict; the corresponding IBP connector will be changed

into on the **MeasureSet** menu as an indication. To remove the IBP conflict, unplug the

conflicting module and re-plug it while less than eight channels of IBP are loaded.

For other modules, only one of the same type is available at a time; another one inserted will be in the conflicting status. For example, if a NIBP module (module A) is loaded then another NIBP module (module B) is inserted, a symbol “!” in red will appear on the corresponding connector on the **MeasureSet** menu to indicate a module conflict. To use module B, directly select the connector of module B on the **MeasureSet** menu, and module A is consequently switched to be in conflicting status.

#### 4.13.1.4 Resolving IBP Label Conflicts

Each label must be unique and can only be assigned once. The measurement labels are stored in the measurement modules. If you try to use two measurement modules that have identical labels, this causes a label conflict in the host monitor.

For example, an IBP module (module A) has already been loaded and the label Art is used for module A. Then another IBP module (module B) is inserted and the label Art is also used for module B. In this case, a label conflict will be triggered. A prompt indicating IBP label conflict will appear on the left of the screen. Additionally, at the corresponding measurements area, two labels flicker to indicate a label conflict. The label inside the brackets is the conflicting one while the label outside the brackets is the default one assigned by the system. Via comparing the labels displayed on the **MeasureSet** menu with the label outside the brackets, you may identify the model with a label conflict and accordingly decide on the module to work.

The IBP module with a label conflict will not provide any measurement data; besides, the functions of setup, zeroing and calibrating are unavailable. To resolve the label conflict, you have to change the conflicting label into a non-conflicting one. Three resolutions are available:

Resolution 1:

- 1 Select the IBP channel with a label conflict on the screen and open the **Options** menu.
- 2 Choose another label among the options from the **Alias** pull-down list to resolve the label conflict.

Resolution 2:

- 1 Deactivate the parameter with label A which works properly or unplug the corresponding module.
- 2 The conflicting label A will consequently turn to be available.

Resolution 3:

- 1 Choose another label for label A which works properly.
- 2 The conflicting label A will consequently turn to be available.

# Chapter 5 Alarms

## **WARNING**

A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.

## 5.1 Alarm Category

The monitor provides two types of alarm: physiological alarms and technical alarms. Also, the monitor provides prompts.

### 5.1.1 Physiological alarms

If one or several physiological parameters of the currently monitored patient exceed the predefined alarm limit, the monitor will give an alarm, and this type of alarm is called physiological alarms. About the detailed alarm information, please refer to the Section *Physiological Alarm Information*.

### 5.1.2 Technical Alarms

If one or several technical status of the device is in abnormal status, the monitor will give an alarm. And this type of alarm is called technical alarms. Technical alarms can't be disabled. About the detailed alarm information, please refer to Section *Technical Alarm Information*.

### 5.1.3 Prompts

The monitor can give the character indication of monitoring process or other functions. And this character is called prompts. About the detailed alarm information, please refer to Section *Prompts*.

## 5.2 Alarm Levels

In terms of severity, the device's alarm levels can be classified into three categories: high level alarms, medium level alarms and low level alarms.

### 1. High level alarms

A high level alarm intensively warns the operator of a high priority alarm condition which requires immediate operator response. Failure to respond to the cause of the alarm condition is likely to result in death or irreversible injury of the patient.

### 2. Medium level alarms

A medium level alarm warns the operator of a medium priority alarm condition which requires prompt operator response. Failure to respond to the cause of the alarm condition is likely to result in reversible injury of the patient.

### 3. Low level alarms

A low level alarm reminds the operator of a low priority alarm condition which requires response. And the response time for a low priority alarm condition can be greater than that for

a medium priority alarm condition. Failure to respond to the cause of the alarm condition is likely to result in discomfort or reversible minor injury of the patient.

## Alarm Sound

The high/medium/low-level alarms are indicated by the system in following different audio ways:

Alarm level	Prompt
High	Mode is “DO-DO-DO-----DO-DO, DO-DO-DO-----DO-DO”, which is triggered once every 10 seconds. The alarm indicator flashes in red, with frequency of 1.4 Hz~2.8 Hz. The alarm message flashes with red background, and the symbol *** is displayed at the alarm area.
Medium	Mode is “DO-DO-DO”, which is triggered once every 25 seconds. The alarm indicator flashes in yellow, with frequency of 0.4 Hz~0.8 Hz. The alarm message flashes with yellow background, and the symbol ** is displayed at the alarm area.
Low	Mode is “DO-”, which is triggered once every 30 seconds. When physiological alarm is triggered, the alarm indicator is constantly yellow. While for technical alarm, the alarm indicator is constantly blue. The alarm message flashes with yellow background, and the symbol * is displayed at the alarm area.

The sound pressure range for audible alarm signals is from 45 dB to 85 dB.

When different level alarms occur at the same time, alarm sound and alarm indicator prompt the highest level alarm, alarm messages display in turn.

The parameter area has two flash methods to prompt alarms: background flash and text flash. User can select one method from **Menu > Alarm Setup > Visual Effect**:

1. **Text Flash**: text flashes with frequency of 1 Hz.
2. **Background Flash**: background flashes with frequency of 1 Hz.

### **WARNING**

- 1 Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.
- 2 Ensure the volume is properly set up. When the sound pressure of audible alarm is below or equivalent to the ambient noise, it may be difficult for the operator to distinguish the audio alarm.

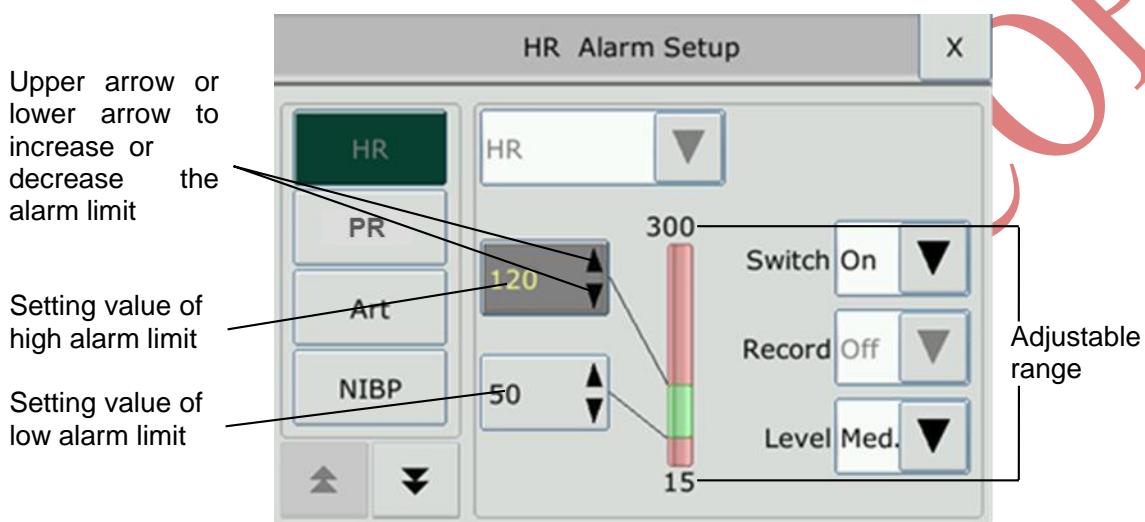
## 5.3 Controlling Alarm

### 5.3.1 Setting Parameter Alarm

Parameter alarm settings including alarm switch, alarm level and alarm limit are available on the respective alarm setup menu for each parameter. To access the menu for parameter alarm settings,

use the shortcut key  or select **Menu > Alarm Setup**, and then click **Alarm Options** to open the menu shown below for alarm settings of each parameter. Also, you can access this menu via the respective parameter setup menu.

When alarm switch is off, the parameter alarm off icon  will be displayed in the corresponding parameter area.



#### **WARNING**

- 1 When the alarm is set to **Off**, the monitor won't give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient's life, the user should use this function cautiously.
- 2 Prior to monitoring, make sure that the alarm limit settings are appropriate for your patient.
- 3 Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is recommended to use the default settings.
- 4 **No alarms** are available on the monitor when connected to a host monitor. Alarms become active again as soon as the monitor is disconnected from the host monitor.
- 5 Alarm fields and other visual alarm indication are disabled on the monitor when connected to a host monitor. The only visual indication is provided by the alarm indicators, which are controlled by the host monitor.
- 6 In HR alarm limit setting process, the bottom will display ExtremeTachy or ExtremeBrady threshold value that has been set. HR high alarm limit should be less than or equal to ExtremeTachy threshold value, and HR low alarm limit should be more than or equal to ExtremeBrady threshold value.

### 5.3.2 Audio Alarm Paused



You can temporarily prevent alarms from sounding by pressing the hardkey on the front panel or pressing the shortcut key on the shortcut widget screen.

You can set the alarm pause time as desired. The default alarm pause time is 120 s.

1. Select **Menu > Maintenance > User Maintain**, and enter the required password.
2. Select **Alarm Setup**, and set **Pause Time** to **60 s, 120 s, or 180 s**.

When alarms are paused,

- ◆ The audio alarm is turned off, and no alarms are sounding.
- ◆ The visual alarm indications are still displayed.
- ◆ The monitor displays the audio alarm paused icon
- ◆ The monitor displays the remaining pause time in seconds with red background.
- ◆ The hardkey on the front panel flashes in yellow.

When the alarm pause time expires, the audio alarm paused status is automatically terminated and alarm is sounding. You can also terminate the alarm paused status by pressing the hardkey .

#### **NOTE:**

If a new alarm occurs during the audio alarm paused period, the new alarm will not be sounding.

### 5.3.3 Audio Alarm off



Set **Pause Time to Permanent**, press hardkey or shortcut key , the monitor displays information: **please confirm whether to activate audio alarm off function?** Click **Yes**, the monitor will enter into audio alarm off status. Click **No**, the monitor will keep current status.

During the audio alarm off status,

- The audio alarm is turned off, and no alarms are sounding.
- The visual alarm indications are still displayed.
- The hardkey on the front panel flashes in yellow.

**Remind signal:** Audio alarm off symbol and **Audio Alarm off** on a red colored background are displayed with an interval of 2 s during the audio alarm off status. If data transferring is in progress at the meantime, the remind signal for audio alarm off will disappear till the data transferring is finished.



Pressing the hardkey again can resume the audio alarm.

**NOTE:**

If a new alarm occurs during the audio alarm off period, the new alarm will not be sounding.

### 5.3.4 Alarm Reset



Select the shortcut key **Alarm Reset** on the screen directly. When the alarm is reset,

- ◆ No alarms are sounding until a new alarm occurs.
- ◆ As for the active alarms, the visual alarm indications are still displayed.
- ◆ All latching alarms are cleared. If the alarm condition is no longer present, all alarm indications stop and the alarm is reset.
- ◆ It will not influence the configuration of physiological alarm off, audio paused, and audio off status.

**NOTE:**

If a new alarm occurs after the alarm is reset, the new alarm will be sounding.

## 5.4 Latching Alarms

To configure the alarm latching setting, select **Menu > Maintenance > User Maintain > Alarm Setup** and choose **Alarm Latch** which can be set to **On** or **Off**. When it is set to **Off**, alarm indications end when the alarm condition ends. When it is set to **On**, the visual and audible alarm indication are still displayed after the alarm condition ends; meanwhile, the alarm time is also displayed for the latched alarm for your reference. The indication lasts until you acknowledge the alarm.



You can use the permanent key on the screen to acknowledge the latched alarm.

## 5.5 Disabling Sensor off Alarms

To set sensor off alarm, please select **Menu > Maintenance > User Maintain** and enter the required password. Then select **Alarm Setup** and set **Sensor Off Alm** from the pull-down list. If



it is set to **On**, and a sensor off alarm occurs, after pressing the hardkey or permanent key



the user can disable the audio alarm signal, however, the visual alarm indications are still



displayed. If it is set to **Off**, and a sensor off alarm occurs, after pressing the hardkey



or permanent key, sensor-off status will be announced with a prompt message. It means there's no audio alarm signal and alarm indicator, but prompt information displayed.

In **Menu > Maintenance > User Maintain > Alarm Setup**, **SpO<sub>2</sub> Sensor Off** and **ECG Lead Off** alarm level can be adjusted as **High**, **Med.** or **Low**. These alarm levels are set to **Low** by default.

## 5.6 Network Disconnected Alarms

To configure the network disconnected alarms, select **Menu > Maintenance > User Maintain > Alarm Setup** and choose **Disconnect Alarm** which can be set to **On** or **Off**. The alarm is off by default.

**NOTE:**

- 1 When the monitor is connected with the central monitoring system, you must set **Disconnect Alarm** to **On**.
- 2 If **Disconnect Alarm** occurs during audio alarm paused or audio alarm off status, the monitor will prompt a sounding alarm with information of **NetWork Disconnect**. During the network disconnected status, activating audio alarm paused or audio alarm off function can disable the audio alarm signal of **Disconnect Alarm**.

## 5.7 Testing Alarms

When you switch the monitor on, the monitor will prompt a “Di” tone that means the audio in selftest is normal. Meantime, you must check that the alarm indicator lights are normal. This indicates that the visible and audible alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

# Chapter 6 Alarm Information

## 6.1 Physiological Alarm Information

### **WARNING**

The physiological alarms including **Asystole**, **Sustain VT**, **RESP APNEA**, **SpO<sub>2</sub> No Pulse**, **SpO<sub>2</sub> Desat**, and **CO<sub>2</sub> APNEA** cannot be turned off.

Message	Cause	Alarm level
<b>ECG</b>		
<b>HR High</b>	HR measuring value is above the upper alarm limit.	User-selectable
<b>HR Low</b>	HR measuring value is below the lower alarm limit.	User-selectable
<b>ST-X High</b>	ST measuring value is above the upper alarm limit. (X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)	User-selectable
<b>ST-X Low</b>	ST measuring value is below the lower alarm limit.(X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)	User-selectable
<b>Asystole</b>	No QRS is detected for 4 consecutive seconds	High
<b>V-Fib/V-Tach</b>	4 consecutive seconds' fibrillation wave occurs; Or 5 consecutive ventricular beats, and ventricular HR $\geq 100$ bpm.	High
<b>Couplet</b>	2 consecutive PVCs	User-selectable
<b>Run PVCs</b>	$3 \leq$ the number of consecutive PVCs $< 5$	User-selectable
<b>PVC Bigeminy</b>	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.	User-selectable
<b>PVC Trigeminy</b>	A dominant rhythm of N, N, V, N, N, V	User-selectable
<b>R on T</b>	A type of single PVC under the condition that HR $< 100$ , R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).	User-selectable
<b>PVC</b>	Single PVC detected in normal heartbeats, and the number of consecutive single PVC $\geq 4$ within 30 s.	User-selectable

Message	Cause	Alarm level
<b>Tachy</b>	Adult: RR interval for 5 consecutive QRS complex $\leq$ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\leq$ 0.375 s.	User-selectable
<b>Brady</b>	Adult: RR interval for 5 consecutive QRS complex $\geq$ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\geq$ 1 s.	User-selectable
<b>Missed Beat</b>	Basic: If HR $<$ 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR $\geq$ 120 bpm, no beats are detected for one second; or no valid QRS wave is detected within 3 s or longer.  Advanced: If HR $<$ 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR $\geq$ 120 bpm, no beats are detected for one second.	User-selectable
<b>Irr Rhythm</b>	Consistently irregular heart rhythm	User-selectable
<b>Pacer not Capture</b>	No QRS complex detected in 300 ms after a pace pulse.	User-selectable
<b>Pacer not Pacing</b>	No pace pulse detected in 1.75 times RR interval after a QRS complex.	User-selectable
<b>Vent Brady</b>	Basic: 5 consecutive ventricular beats, and ventricular HR $<$ 40 bpm.  Advanced: 5 consecutive ventricular beats, and ventricular HR $<$ 20 bpm.	High
<b>Vent Rhythm</b>	Basic: 5 consecutive ventricular beats, and 40 bpm $\leq$ ventricular HR $<$ 100 bpm.  Advanced: 5 consecutive ventricular beats, and 20 bpm $\leq$ ventricular HR $<$ 40 bpm.	User-selectable
<b>Sustain VT</b>	The duration of ventricular tachycardia rhythm $\geq$ the threshold value that has been set.	High
<b>ExtremeTachy</b>	HR $\geq$ Extreme Tachycardia threshold value that has been set.	High

Message	Cause	Alarm level
<b>ExtremeBrady</b>	HR $\leq$ Extreme Bradycardia threshold value that has been set.	High
<b>V-Tach</b>	5 consecutive ventricular beats and ventricular HR $\geq$ 100 bpm.	High
<b>Wide QRS Tachy</b>	Meet tachycardia conditions, and QRS wave width $\geq$ 160 ms.	User-selectable
<b>Non-Sustain VT</b>	3 $\leq$ The number of consecutive ventricular beats $< 5$ , and ventricular HR $\geq$ 100 bpm.	User-selectable
<b>Afib</b>	Atrial fibrillation alarm should meet below two conditions for 1 minute: the RR interval of normal beats must be irregular, and it can be seen that the obvious f or P waves do not exist.	User-selectable
<b>Acc. Vent Rhythm</b>	5 consecutive ventricular beats, and 40 bpm $\leq$ ventricular HR $<$ 100 bpm.	User-selectable
<b>Pause</b>	No QRS is detected within the heartbeat pause threshold value that has been set.	User-selectable
<b>Pauses/min High</b>	The measurement value of Pause/min is greater than high alarm limit that has been set.	User-selectable
<b>PVCs High</b>	The measurement value of PVCs is greater than high alarm limit that has been set.	User-selectable
<b>VEB</b>	The delayed ventricular beats detected in normal heartbeats occur more than or equal to 2 times within 30 s.	User-selectable
<b>Multiform PVCs</b>	Different forms of ventricular premature beats are detected in 15 beats.	User-selectable
<b>IPVC</b>	The single ventricular premature beat between 2 sinus beats with normal interval occurs more than or equal to 3 times within 30 s.	User-selectable
<b>PAC Bigeminy</b>	The dominant rhythm of N, A, N, A, N, A, and the rhythm number exceeds the number of threshold value that has been set (N = supraventricular beat, A = atrial beat).	User-selectable
<b>PAC Trigeminy</b>	The dominant rhythm of N, N, A, N, N, A, N, N, A, and the rhythm number exceeds the number of threshold value that has been set.	User-selectable

Message	Cause	Alarm level
<b>Low Voltage(Limb)</b>	None of the signal amplitudes of I, II and III leads exceeds that of the alarm threshold that has been set. PS: this alarm is available for 5, 6 or 10 electrodes only, not available for 3 electrodes.	User-selectable
<b>QTc High</b>	QTc measuring value is above upper alarm limit.	User-selectable
<b>ΔQTc High</b>	ΔQTc measuring value is above upper alarm limit.	User-selectable
<b>RESP</b>		
<b>RESP APNEA</b>	RESP waveform cannot be detected within the set apnea alarm delay time.	High
<b>RR High</b>	RR measuring value is above upper alarm limit.	User-selectable
<b>RR Low</b>	RR measuring value is below lower alarm limit.	User-selectable
<b>SpO<sub>2</sub></b>		
<b>SpO<sub>2</sub> High</b>	SpO <sub>2</sub> measuring value is above upper alarm limit.	User-selectable
<b>SpO<sub>2</sub> Low</b>	SpO <sub>2</sub> measuring value is below lower alarm limit.	User-selectable
<b>SpO<sub>2</sub> No Pulse</b>	The signal of the measurement site is too weak due to insufficient blood supply and environmental factors, so the monitor can't detect the pulse signal.	High
<b>SpO<sub>2</sub> Desat</b>	SpO <sub>2</sub> measuring value is below the SpO <sub>2</sub> Desat Limit.	High
<b>PR High</b>	PR measuring value is above upper alarm limit.	User-selectable
<b>PR Low</b>	PR measuring value is below lower alarm limit.	User-selectable
<b>TEMP</b>		
<b>T1 High</b>	Measuring value of T1 channel is above upper alarm limit.	User-selectable
<b>T1 Low</b>	Measuring value of T1 channel is below lower alarm limit.	User-selectable
<b>T2 High</b>	Measuring value of T2 channel is above upper alarm limit.	User-selectable
<b>T2 Low</b>	Measuring value of T2 channel is below lower alarm limit.	User-selectable
<b>TD High</b>	Measuring value of TD channel is above upper alarm limit.	User-selectable
<b>NIBP</b>		
<b>SYS High</b>	SYS measuring value is above upper alarm limit.	User-selectable
<b>SYS Low</b>	SYS measuring value is below lower alarm limit.	User-selectable
<b>DIA High</b>	DIA measuring value is above upper alarm limit.	User-selectable

Message	Cause	Alarm level
<b>DIA Low</b>	DIA measuring value is below lower alarm limit.	User-selectable
<b>MAP High</b>	MAP measuring value is above upper alarm limit.	User-selectable
<b>MAP Low</b>	MAP measuring value is below lower alarm limit.	User-selectable
<b>PR (NIBP) High</b>	PR measuring value from the NIBP module is above upper alarm limit.	User-selectable
<b>PR (NIBP) Low</b>	PR measuring value from the NIBP module is below lower alarm limit.	User-selectable
<b>IBP</b>		
<b>Art SYS High</b>	Art SYS measuring value is above upper alarm limit.	User-selectable
<b>Art SYS Low</b>	Art SYS measuring value is below lower alarm limit.	User-selectable
<b>Art DIA High</b>	Art DIA measuring value is above upper alarm limit.	User-selectable
<b>Art DIA Low</b>	Art DIA measuring value is below lower alarm limit.	User-selectable
<b>Art MAP High</b>	Art MAP measuring value is above upper alarm limit.	User-selectable
<b>Art MAP Low</b>	Art MAP measuring value is below lower alarm limit.	User-selectable
<b>PA SYS High</b>	PA SYS measuring value is above upper alarm limit.	User-selectable
<b>PA SYS Low</b>	PA SYS measuring value is below lower alarm limit.	User-selectable
<b>PA DIA High</b>	PA DIA measuring value is above upper alarm limit.	User-selectable
<b>PA DIA Low</b>	PA DIA measuring value is below lower alarm limit.	User-selectable
<b>PA MAP High</b>	PA MAP measuring value is above upper alarm limit.	User-selectable
<b>PA MAP Low</b>	PA MAP measuring value is below lower alarm limit.	User-selectable
<b>CVP MAP High</b>	CVP MAP measuring value is above upper alarm limit.	User-selectable
<b>CVP MAP Low</b>	CVP MAP measuring value is below lower alarm limit.	User-selectable
<b>ICP MAP High</b>	ICP MAP measuring value is above upper alarm limit.	User-selectable
<b>ICP MAP Low</b>	ICP MAP measuring value is below lower alarm limit.	User-selectable
<b>LAP MAP High</b>	LAP MAP measuring value is above upper alarm limit.	User-selectable
<b>LAP MAP Low</b>	LAP MAP measuring value is below lower alarm limit.	User-selectable
<b>RAP MAP High</b>	RAP MAP measuring value is above upper alarm limit.	User-selectable
<b>RAP MAP Low</b>	RAP MAP measuring value is below lower alarm limit.	User-selectable
<b>P1 SYS High</b>	P1 SYS measuring value is above upper alarm limit.	User-selectable
<b>P1 SYS Low</b>	P1 SYS measuring value is below lower alarm limit.	User-selectable
<b>P1 DIA High</b>	P1 DIA measuring value is above upper alarm limit.	User-selectable
<b>P1 DIA Low</b>	P1 DIA measuring value is below lower alarm limit.	User-selectable
<b>P1 MAP High</b>	P1 MAP measuring value is above upper alarm limit.	User-selectable

Message	Cause	Alarm level
<b>P1 MAP Low</b>	P1 MAP measuring value is below lower alarm limit.	User-selectable
<b>P2 SYS High</b>	P2 SYS measuring value is above upper alarm limit.	User-selectable
<b>P2 SYS Low</b>	P2 SYS measuring value is below lower alarm limit.	User-selectable
<b>P2 DIA High</b>	P2 DIA measuring value is above upper alarm limit.	User-selectable
<b>P2 DIA Low</b>	P2 DIA measuring value is below lower alarm limit.	User-selectable
<b>P2 MAP High</b>	P2 MAP measuring value is above upper alarm limit.	User-selectable
<b>P2 MAP Low</b>	P2 MAP measuring value is below lower alarm limit.	User-selectable
<b>CO<sub>2</sub></b>		
<b>EtCO<sub>2</sub> High</b>	EtCO <sub>2</sub> measuring value is above upper alarm limit.	User-selectable
<b>EtCO<sub>2</sub> Low</b>	EtCO <sub>2</sub> measuring value is below lower alarm limit.	User-selectable
<b>FiCO<sub>2</sub> High</b>	FiCO <sub>2</sub> measuring value is above alarm limits.	User-selectable
<b>CO<sub>2</sub> APNEA</b>	In the set apnea alarm delay time interval, no RESP can be detected using CO <sub>2</sub> module.	High
<b>AwRR High</b>	AwRR measuring value is above upper alarm limit.	User-selectable
<b>AwRR Low</b>	AwRR measuring value is below lower alarm limit.	User-selectable
<b>CI High</b>	CI measuring value is above upper alarm limit.	User-selectable
<b>CI Low</b>	CI measuring value is below lower alarm limit.	User-selectable

## 6.2 Technical Alarm Information

### NOTE:

The ECG alarm information listed in the below table describes the electrode names in America. For the corresponding electrode names in Europe, please refer to the Section *Installing Electrodes*.

Message	Cause	Alarm Level	Action Taken
<b>ECG</b>			
<b>ECG Lead Off</b>	1) The drive electrode or more than one ECG limb electrode falls off the skin; 2) ECG cables fall off the monitor.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
<b>ECG LL Lead Off</b>	ECG electrode LL falls off the skin or the ECG cable LL falls off the monitor.	Low	Make sure that all electrodes, leads and patient cables are properly connected.

Message	Cause	Alarm Level	Action Taken
<b>ECG LA Lead Off</b>	ECG electrode LA falls off the skin or the ECG cable LA falls off the monitor.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
<b>ECG RA Lead Off</b>	ECG electrode RA falls off the skin or the ECG cable RA falls off the monitor.	Low	
<b>ECG RL Lead Off</b>	When electrode type is AUTO, ECG electrode RL falls off the skin or the ECG cable RL falls off the monitor, 5/6/10 electrode switches to 3 electrodes;	Low	Make sure that all electrodes, leads and patient cables are properly connected.
<b>ECG V Lead Off</b>	ECG electrode V falls off the skin or the ECG cable V falls off the monitor.	Low	
<b>ECG V1 Lead Off</b>	ECG electrode V1 falls off the skin or the ECG cable V1 falls off.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
<b>ECG V2 Lead Off</b>	ECG electrode V2 falls off the skin or the ECG cable V2 falls off.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
<b>ECG V3 Lead Off</b>	ECG electrode V3 falls off the skin or the ECG cable V3 falls off.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
<b>ECG V4 Lead Off</b>	ECG electrode V4 falls off the skin or the ECG cable V4 falls off.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
<b>ECG V5 Lead Off</b>	ECG electrode V5 falls off the skin or the ECG cable V5 falls off.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
<b>ECG V6 Lead Off</b>	ECG electrode V6 falls off the skin or the ECG cable V6 falls off.	Low	Make sure that all electrodes, leads and patient cables are properly connected.

Message	Cause	Alarm Level	Action Taken
<b>ECG Signal Exceed</b>	ECG measuring signal is beyond measuring range.	Low	Check lead connection and patient condition
<b>ECG Comm Fail</b>	ECG module failure or communication failure	High	Stop measuring function of ECG module, and notify biomedical engineer or manufacturer's service staff.
<b>ECG Noise</b>	ECG measuring signal is greatly interrupted.	Low	Check lead connection and patient condition
<b>RESP</b>			
<b>RESP Comm Fail</b>	RESP module failure or communication failure	High	Stop measuring function of RESP module, and notify biomedical engineer or the manufacturer's service staff.
<b>RESP Noise</b>	RR cannot be measured due to patient movement.	Low	Check whether the RESP leads are well connected. Keep the patient calm for better monitoring.
<b>RR Exceed</b>	RR measuring value is out of the measure range.	Medium	Check whether interference to the respiratory signal exists. And check whether the patient is breathing normally; breathing too rapidly or too slowly may endanger patient's life.

Message	Cause	Alarm Level	Action Taken
<b>RESP Artifact</b>	<b>Cardiac</b> No RESP waveform can be detected due to apnea or shallow breathing of the patient.	High	Check whether the patient is breathing normally. Take measures to help the patient breathe normally when necessary. If the patient is breathing normally, try to adjust the electrode position on the patient in order to reduce the interference of carcinogenic artifact.
<b>SpO<sub>2</sub></b>			
<b>SpO<sub>2</sub> Sensor Off</b>	SpO <sub>2</sub> sensor may be disconnected from the patient or the monitor.	Low	Make sure the sensor is well connected to the patient's finger or other parts. Make sure the monitor and cables are well connected.
<b>SpO<sub>2</sub> Comm Fail</b>	SpO <sub>2</sub> module failure or communication failure	High	Stop using measuring function of SpO <sub>2</sub> module, and notify biomedical engineer or manufacturer's service staff.
<b>SpO<sub>2</sub> Sensor Err</b>	Malfunction in the SpO <sub>2</sub> sensor or in the extension cable.	Low	Replace the SpO <sub>2</sub> sensor or the extension cable.
<b>SpO<sub>2</sub> No Sensor</b>	SpO <sub>2</sub> sensor may be disconnected from the patient or the monitor.	Low	Make sure the sensor is well connected to the patient's finger or other parts. Make sure the monitor and cables are well connected.

Message	Cause	Alarm Level	Action Taken
<b>SpO<sub>2</sub> Low Perfusion</b>	The pulse signal is too weak or the perfusion of the measurement site is too low. The SpO <sub>2</sub> value and PR value might be inaccurate then.	Low	Reconnect the SpO <sub>2</sub> sensor and change the measurementsite. If problem exists, please notify biomedical engineer or manufacturer's service staff.
<b>SpO<sub>2</sub> Noisy Signal (ELITECH SpO<sub>2</sub> module)</b>	There is interference with SpO <sub>2</sub> measurement signals due to patient movement, ambient light, electrical interference or else.	Low	Check the condition of patient and avoid patient movement; make sure the cable is well connected.
<b>SpO<sub>2</sub> Light Interference</b>	Ambient light around the sensor is too strong.	Low	Reduce interference of the ambient light and avoid sensor's exposure to strong light.
<b>NIBP</b>			
<b>NIBP Comm Fail</b>	NIBP module failure or communication failure	High	Stop using measuring function of NIBP module, and notify biomedical engineer or manufacturer's service staff.
<b>NIBP Time Out</b>	Measuring time has exceeded the specified time.	Low	Measure again or use other measuring method.
<b>NIBP Pressure Excessive</b>	Pressure has exceeded the specified upper safety limit.	Low	Measure again, if failure persists, stop measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
<b>NIBP Init Pressure High</b>	The initial pressure is too high during measuring	Low	Measure again, if failure persists, stop measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.

Message	Cause	Alarm Level	Action Taken
<b>NIBP Self Test Error</b>	Sensor or other hardware errors.	High	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
<b>NIBP Cuff Type Error</b>	The cuff type used isn't consistent with the patient type.	Low	Confirm the patient type and change the cuff.
<b>NIBP System Failure</b>	NIBP is not calibrated.	High	Contact your service personnel.
<b>NIBP Weak Signal</b>	Cuff is too loose or patient pulse is too weak.	Low	
<b>NIBP Range Exceeded</b>	All of the SYS, DIA and MAP value are beyond the measurement range.	High	
<b>SYS(NIBP) Overrange</b>	SYS (NIBP) value is beyond the measurement range.	High	Use other methods to measure blood pressure.
<b>DIA(NIBP) Overrange</b>	DIA (NIBP) value is beyond the measurement range.	High	
<b>MAP(NIBP) Overrange</b>	MAP (NIBP) value is beyond the measurement range.	High	
<b>NIBP Loose Cuff</b>	Cuff is not properly wrapped or no cuff is connected.	Low	Properly wrap the cuff.
<b>NIBP Interference</b>	Signal noise is too large or pulse rate is not regular due to the patient movement.	Low	Make sure that the patient under monitoring is motionless.

Message	Cause	Alarm Level	Action Taken
<b>NIBP Aux Excessive Pressure</b>	Pressure has exceeded the second safety limit as specified.	High	Notify biomedical engineer or manufacturer's service staff.
<b>NIBP Leak Test Error</b>	Fail to deflate normally during the leak test, so NIBP leak test cannot be finished.	Low	Test again. If the problem still exists, contact your service personnel.
<b>NIBP Airway Pressure Abnormality</b>	Atmospheric pressure or system pressure is abnormal. The valve is occluded so that deflation is failed.	Low	Check whether the airway is occluded or pressure sensor works properly. If the problem still exists, contact your service personnel.
<b>NIBP Leak</b>	NIBP pump, valve, cuff or tube has a leakage.	Low	Check the connections and the wrapped cuff to see whether they are all prepared well. If failure persists, please notify biomedical engineer or manufacturer's service staff.
<b>TEMP</b>			
<b>TEMP T1 Sensor Off</b>	Temperature cable of TEMP channel1 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected
<b>TEMP T2 Sensor Off</b>	Temperature cable of TEMP channel2 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected.
<b>Excessive T1</b>	TEMP1 measuring value is beyond measuring range.	High	Check sensor connection and patient condition

Message	Cause	Alarm Level	Action Taken
<b>Excessive T2</b>	TEMP2 measuring value is beyond measuring range.	High	
<b>TEMP Comm Fail</b>	TEMP module failure or communication failure.	High	Stop measuring function of TEMP module, and notify biomedical engineer or Manufacturer's service staff.
<b>T1 Calibration Failed</b>	T1 calibration failed.	High	Please check whether the module works properly.
<b>T2 Calibration Failed</b>	T2 calibration failed	High	
<b>IBP</b>			
<b>YY Sensor Off</b> (YY stands for the IBP label name)	IBP sensor falls off.	Medium	Check the sensor connection and reconnect the sensor.
<b>YY Comm Fail</b> (YY stands for the IBP label name: Art, PA, CVP, RAP, LAP, ICP, P1 and P2)	IBP module failure or communication failure	High	Stop measuring function of IBP module, and notify biomedical engineer or Manufacturer's service staff.
<b>IBP Catheter Off</b>	IBP catheter falls off due to patient movement.	High	Check the catheter connection and reconnect it.
<b>IBP Sensor Err</b>	Malfunction in the IBP sensor or in the extension cable.	Medium	Replace the IBP sensor or the extension cable.
<b>CO<sub>2</sub></b>			
<b>CO<sub>2</sub> Comm. Failed</b>	CO <sub>2</sub> module failure or communication failure	High	Check if the water tray has been fixed.
<b>CO<sub>2</sub> Occlude</b>	Sampling cannula is occluded or distorted.	High	Make sure the gas exhaust works well

Message	Cause	Alarm Level	Action Taken
<b>CO<sub>2</sub> Zero Required</b>	Zero calibration failure	Low	Disconnect the sampling cannula or adapter from the airway; initiate the zeroing before making sure that no expired air is inside the sampling cannula and adapter.
<b>CO<sub>2</sub> Check Adapter</b>	The cannula is off or disconnected.	Low	Check whether the adapter is properly connected or replace the adapter.
<b>CO<sub>2</sub> Sensor Faulty</b>	CO <sub>2</sub> module failure	High	Stop measuring function of CO <sub>2</sub> module, notify biomedical engineer.
<b>CO<sub>2</sub> Sensor Over Temp</b>	CO <sub>2</sub> measure value exceeds the measure range of the monitor.	High	Stop measuring function of CO <sub>2</sub> module, notify biomedical engineer.
<b>EtCO<sub>2</sub> Overrange</b>	The EtCO <sub>2</sub> concentration exceeds the measurement range.	High	Please check the monitor or patient status and adjust the gas concentration accordingly.
<b>FiCO<sub>2</sub> Overrange</b>	The FiCO <sub>2</sub> concentration exceeds the measurement range.	High	
<b>C.O.</b>			
<b>C.O. Comm Fail</b>	C.O. module failure or communication failure	High	Stop measuring of C.O. module, or notify biomedical engineer or Manufacturer's service staff.
<b>C.O. TI Sensor Off</b>	C.O. TI sensor not connected	Low	Insert injective temperature sensor.

Message	Cause	Alarm Level	Action Taken
<b>C.O. TB Sensor Off</b>	C.O. TB sensor not connected	Low	Insert TB sensor.
<b>C.O. TEMP Out Of Range</b>	TI/TB measuring value is beyond measuring range.	High	Please check TI/TB sensor.
<b>Others</b>			
<b>Battery Low</b>	Battery Low	High	Please change the battery or charging.
<b>Not Insert Battery</b>	No battery is plugged in.	Medium	Plug in the battery.
<b>Battery Error</b>	Malfunction in Battery.	Low	Replace the battery and restart the monitor. If the problem persists, notify the manufacturer's service staff.
<b>Network Disconnect</b>	In distributed alarm system, the monitor's network is disconnected.	Low	<ul style="list-style-type: none"> <li>1) Check if the network cable is well connected.</li> <li>2) Check if the MFM-CMS is turned on.</li> <li>3) Check if the IP of bedside monitor and MFM-CMS are on the same network segment.</li> </ul>

Message	Cause	Alarm Level	Action Taken
<b>Network traffic anomaly</b>	Abnormal network traffic has been detected. The data traffic exceeds the limit.	High	Disconnect the network to make the monitor work properly, and then contact the professionals authorized by manufacturer to check the network problem.
<b>Insufficient storage space</b>	Less than 10 M space is left in the storage device.	Low	Delete some data in the storage device or use another removable device.
<b>Read-only storage device</b>	The storage device is read-only.	Low	Repair the storage device or replace it with a new one.
<b>Storage device damaged</b>	Storage device is damaged.	Low	

### 6.3 Prompts

Message	Cause
<b>ECG ARR Learning</b>	The QRS template building required for Arr. Analysis is in process.
<b>Unable to analyze ST</b>	The ST algorithm cannot produce valid ST value, which may be caused by the large change in the measured value of connected cardiogram ST or ventricular pacing.
<b>Unable to analyze QT</b>	QT algorithm cannot generate valid QT for more than 10 minutes (or 1 minute during startup).
<b>QT Baseline Overrange</b>	After modifying the calculation formula, the QTc parameter value exceeds the range.
<b>Unable to analyze ECG</b>	The arrhythmia algorithm cannot analyze ECG data reliably.
<b>V-Fib/V-Tach Off</b>	V-Fib/V-Tach alarm is set to <b>Off</b> .

Message	Cause
<b>ExtremeTachy Off</b>	Extreme Tachycardia alarm is set to <b>Off</b> .
<b>ExtremeBrady Off</b>	Extreme Bradycardia alarm is set to <b>Off</b> .
<b>V-Tach Off</b>	V-Tach alarm is set to <b>Off</b> .
<b>Vent Brady Off</b>	Vent Brady alarm is set to <b>Off</b> .
<b>Key ARR Alarm Off</b>	One of Key ARR alarms is set to <b>Off</b> .
<b>Electrode Contact Poor</b>	The electrode has bad contact with patient's body.
<b>SpO<sub>2</sub> Search Pulse</b>	SpO <sub>2</sub> module is analyzing the patient signal and searching for the pulse to compute the saturation, when sensor is connected with patient.
<b>Manual Measuring</b>	In manual measuring mode.
<b>Continual Measuring</b>	In continuous measuring mode.
<b>Auto Measuring</b>	In automatic measuring mode.
<b>Sequence Measuring</b>	In sequence measuring mode.
<b>Measure. Canceled</b>	Press the button  or shortcut key  to stop the measurement.
<b>Calibrating</b>	During calibrating
<b>Calibrat. Canceled</b>	Calibration is over.
<b>Leak Testing</b>	During pneumatic test
<b>Leak.Test Canceled</b>	Pneumatic test over
<b>Resetting</b>	NIBP module in resetting
<b>Please Start</b>	NIBP module is in idle status
<b>Done</b>	NIBP measurement is completed.
<b>Venipuncture Starting</b>	Start the assisting venipuncture and the cuff begins to inflate.
<b>In venipuncture process</b>	Venipuncture in process
<b>Venipuncture Ending</b>	Finish the assisting venipuncture and the cuff begins to deflate.
<b>Be sure the cuff is disconnected from monitor</b>	In Cleaning Mode, the user clicks the <b>Start Cleaning</b> button.
<b>Cleaning succeeded</b>	Cleaning finished successfully.
<b>Cleaning failed</b>	Abnormal air pressure in cleaning mode.
<b>Cleaning in progress</b>	The monitor is in cleaning progress.

Message	Cause
<b>CO<sub>2</sub> Standby</b>	Switch from measuring mode to standby mode, making the module in energy-saving status.
<b>CO<sub>2</sub> Sensor Warm Up</b>	The CO <sub>2</sub> module is in warm-up state
<b>Zeroing...</b>	The CO <sub>2</sub> module is performing the zero calibration.
<b>CO<sub>2</sub> Zero Start</b>	CO <sub>2</sub> module starts zero calibration.
<b>CO<sub>2</sub> Zero OK</b>	CO <sub>2</sub> module completes zero calibration.
<b>C.O. Lack Param</b>	Parameter is not configured for C.O. measurement.
<b>Please Press 'Zero'.</b>	Enter the IBP zeroing menu, and zeroing is not performed yet.
<b>Zero OK</b>	IBP completes zeroing.
<b>Pulsatile Pressure Zero Fail.</b>	During the zeroing process, pressure fluctuation is excessive.
<b>Pressure out of normal range,Fail.</b>	During the zeroing process, pressure value is beyond the zeroing range.
<b>Sensor Off, Fail!</b>	Perform zeroing when the sensor is off.
<b>Invalid Time,Zero Fail.</b>	Time is not set up prior zeroing.
<b>Unable to Calibrate in Demo Mode</b>	Perform zeroing in Demo Mode.
<b>Zeroing...</b>	Zeroing is in progress.
<b>Please Press 'Calibrate'.</b>	Enter the Calibration menu, and Calibration is not performed yet.
<b>Calibration OK</b>	Calibration is completed.
<b>Pulse Pressure Calibration Failed</b>	During the Calibration process, pressure fluctuation is excessive.
<b>Pressure out of range</b>	During the Calibration process, pressure value is beyond the Calibration range.
<b>Zeroing and Calibration Failed</b>	Zeroing is not performed prior calibration.
<b>Sensor Off,Fail.</b>	Perform calibration when the sensor is off.
<b>Invalid Time,Calibration Fail.</b>	Time is not set up prior calibration.
<b>Unable to Calibrate in Demo Mode</b>	Perform calibration in Demo Mode.
<b>Calibrating...</b>	Calibration is in progress.
<b>IBP alias collision</b>	The same IBP label appears.
<b>Transfer data...</b>	The monitor is transferring data to the target monitor.

Message	Cause
<b>In transfer status</b>	After pressing the Transfer Patient key, the monitor is ready for transferring data.
<b>Incomplete parameter input, unable to score</b>	In MEWS interface, parameters are not completely input.
<b>SpO<sub>2</sub> Noisy Signal</b> (Nellcor SpO <sub>2</sub> module)	There is interference with SpO <sub>2</sub> measurement signals due to patient movement, ambient light, electrical interference or else.
<b>NIBP Simul</b>	<b>NIBP Simul</b> function is turned on.
<b>The space in U disk is less than 300 M. Please clean it up.</b>	The remaining space of U disk is less than 300 M.
<b>Please input user password first. Attention! Private information included in the data.</b>	When user exports data from the internal storage device.
<b>More than five consecutive password errors</b>	Continuously enter the wrong password for more than 5 times.

## 6.4 Adjustable Range of Alarm Limits

ECG alarm limits are listed as follows: unit (bpm)

	Patient Type	Adjustable Range
HR	ADU	15~300
	PED/NEO	15~350

ST analysis alarm limits are listed as follows: unit (mV)

	Adjustable Range
ST	-2.0~2.0

QTc and ΔQTc alarm limits are listed as follows: unit (ms)

	Adjustable Range
QTc	200~800
ΔQTc	30~200

RESP alarm limits are listed as follows: unit (rpm)

	Patient Type	Adjustable Range
RESP	ADU	6~120
	PED/NEO	6~150

SpO<sub>2</sub> alarm limits are listed as follows: (unit %)

	Adjustable Range
SpO <sub>2</sub>	20~100

SpO<sub>2</sub> Desat Limits are listed as follows (unit %):

	Adjustable Range
SpO <sub>2</sub> Desat Limit	20~99

#### NOTE:

User can set the range through **User Maintain > Alarm Setup > SpO<sub>2</sub> Desat Limit**, SpO<sub>2</sub> Desat Limit should be less than or equal to SpO<sub>2</sub> alarm low limit.

PR alarm limits are listed as follows: unit (bpm)

		Adjustable Range
PR(SpO <sub>2</sub> )	ELITECH	30~300
	Nellcor	30~300
PR(NIBP)	ELITECH	40~240
	SunTech	30~220
PR (IBP)	ELITECH	30~300

NIBP alarm limits are listed as follows: unit (mmHg)

Patient Type		Adjustable Range		
		ELITECH (Applicable for CE registration area)	ELITECH (Applicable for FDA registration area)	SunTech
ADU	SYS	25~290	40~270	40~260
	DIA	10~250	10~215	20~200
	MAP	15~260	20~235	26~220
PED	SYS	25~240	40~230	40~230
	DIA	10~200	10~180	20~160
	MAP	15~215	20~195	26~183

Patient Type		Adjustable Range		
		ELITECH (Applicable forCE registration area)	ELITECH (Applicable forFDA registration area)	SunTech
NEO	SYS	25~140	40~135	40~130
	DIA	10~115	10~100	20~100
	MAP	15~125	20~110	26~110

TEMP alarm limits are listed as follows:

	Adjustable Range
T1	0 °C (32 °F)~50 °C (122 °F)
T2	0 °C (32 °F)~50 °C (122 °F)
TD	High limit: 0.1 °C (32.18 °F)~50 °C (122 °F)

IBP alarm limits are listed as follows: unit (mmHg)

	Adjustable Range
Art	0~300
RAP/LAP/CVP/ICP	-10~40
PA	-6~120
P1/P2	-50~300

CO<sub>2</sub> alarm limits are listed as follows:

	Adjustable Range
EtCO <sub>2</sub>	0 mmHg~150 mmHg
FiCO <sub>2</sub>	High limit: 3 mmHg~50 mmHg
AwRR	Sidestream: 2 rpm~150 rpm

C.O. alarm limits are listed as follows:

	Adjustable Range
TB	23 °C (73.4 °F)~43 °C (109.4 °F)

# Chapter 7 Managing Patients

## 7.1 Confirming a Patient

After the user switches the monitor on, the monitor will prompt “**Continue monitoring the current patient or admit new patient?**”. Select **Current Patient** to use the current configuration; Select **New Patient** to admit new patient.

### NOTE:

If the user does not make a selection within 1 minutes, **Current Patient** is selected by default.

## 7.2 Admitting a Patient

The monitor displays physiological data and stores it in the trends as soon as a patient is connected. This allows you to monitor a patient who is not yet admitted. It is however important to admit patients properly so that you can identify your patient on recordings, reports, and networked devices.

During admission you enter data that the monitor needs for safe and accurate operation. For example, the patient category setting determines the algorithm the monitor uses to process and calculate some measurements, the safety limits that are applied for some measurements, and the alarm limit ranges.

To admit a patient, please:

1. Select the shortcut key  on the shortcut widget screen or.
2. Select **Menu > Patient Setup > New Patient**, then a message is displayed to ask the user to confirm to update patient.
3. Click on **No** to cancel this operation; click on **Yes**, the **Patient Info** window is displayed.
4. Enter the patient information:
  - **MRN:** Enter the patient’s medical record number.
  - **Last Name:** Enter the patient’s last name (family name).
  - **First Name:** Enter the patient’s first name.
  - **Bed No.:** Supports up to 8 characters. Chinese, English, Russian, numbers and special characters can be input.
  - **Doctor:** Enter the attending doctor for the patient.
  - **Gender:** **Male**, **Female** and **N/A**.
  - **Type:** Choose the patient type, either **Adult**, **Pediat**, or **Neonat**.
  - **BloodType:** **N/A**, **A**, **B**, **AB** and **O**.
  - **Pace:** Choose **On** or **Off** (You must select **On** if your patient has a pacemaker).
  - **Date of Birth:** Enter the patient’s date of birth.

- **Date of Admission:** Enter the patient's date of admission.
- **Height:** Enter the patient's height, with unit: **cm** or **inch**.
- **Weight:** Enter the patient's weight, with unit: **kg** or **lb**.

**NOTE:**

- 1 For Bed No., user can select English, Chinese, Russian through switching keyboard language, and select special characters through  #+=.
- 2 Creating new patient and updating patient will clear the history data in the monitor associated with the patient.

### 7.2.1 Patient Category and Paced Status

The patient category setting determines the algorithm which the monitor uses to process and calculate some measurements, the safety limits that are applied for some measurements, and the alarm limit ranges.

The paced setting determines whether the monitor shows pacemaker pulses or not. When **Pace** is set to **Off**, pace pulses are filtered and therefore do not show in the ECG wave.

**WARNING**

- 1 Changing the patient category may change the arrhythmia and NIBP alarm limits. Always check alarm limits to make sure that they are appropriate for your patient.
- 2 For paced patients, you must set Paced to **On**. If it is incorrectly set to **Off**, the monitor could mistake a pace pulse for a QRS and fail to give an alarm during asystole.

### 7.3 Quick Admit

If you do not have the time or information to fully admit a patient, you can use Quick Admit to quickly admit a patient and complete the rest of the patient information later. To quickly admit a patient, please:

1. Select the shortcut key   on the screen directly, or
2. Select **Menu > Patient Setup > Quick Admit**, then a message is displayed to ask the user to confirm to update patient.
3. Click on **No** to cancel this operation; click on **Yes** to continue and the **Quick Admit** window is displayed.
4. Configure **Type** and **Pace** to the correct setting and click **Yes** to finish the quick patient admission operation. If you want to quit the operation, click **No**.

### 7.4 Editing Patient Information

To edit the patient information after a patient has been admitted, select **Menu > Patient Setup > Patient Info.**, and make the required changes on the popup interface.

## 7.5 Transferring Patients

To save you from having to enter the same patient data several times and enable patient transfer without loss of data, the patient information can be shared between the monitor and the host monitor. By connecting the monitor to the host monitor:

- Patient demographic information is shared between the two monitors.
- Trend data (excluding waveforms) and alarm events stored in the monitor can be uploaded to the host monitor, if configured.
- The configuration information (excluding display setup) is synchronized with that of the host monitor, if configured.

### **WARNING**

- 1 If the monitor is not battery-powered, you cannot monitor during transport.
- 2 When the monitor is connected to the host monitor in non-transfer mode, a symbol  is displayed on the screen, and the data in the monitor will be stored in the internal storage device; however, the configuration information is synchronized with that of the host monitor.
- 3 If data transfer fails while the monitor is storing data, then the monitor will store the data as a new file, with a new patient name.

### **NOTE:**

The **Transfer Patient** key is not available while the monitor is connected to a host monitor.

To transfer patients, please:

1. Prior to connecting the monitor to the host monitor, select **Menu > Patient Setup > Transfer Patient**, then a message is displayed to ask the user to confirm to transfer patients.
2. Click on **Confirm** to start patient transferring; click on **Cancel** to exit.
3. When you confirm to transfer patients, a symbol  is displayed on the screen.
4. Connect the monitor to the host monitor. Transfer the patients by the monitor as the transport monitor.

Once they are connected, you may operate the patient transferring on the host monitor.

5. After the connection, a message is displayed on the host monitor to ask the user to confirm the data transfer.
6. Click on **Confirm** to start patient transferring; click on **Cancel** to exit.
7. When you confirm to data transfer, a message **Transfer the patient success** is displayed on the screen, otherwise, **Transfer the patient fail and the monitor will be restored** is displayed.

**NOTE:**

When the data transferring is accidentally interrupted by the user, the history data in the monitor associated with the patient will be changed.

## 7.6 Central Monitoring System

The monitor can be connected to the central monitoring system. Through the network:

- 1 The monitor sends patient information, real-time monitoring or measurement data to the central monitoring system.
- 2 The real-time monitoring information is displayed on the central monitoring system as the same to the monitor, and the central monitoring system can perform some bilateral control. For example: changing patient information, receiving patient, discharging patient and so forth.

For detailed information, please refer to *MFM-CMS Central Monitoring System User Manual*.

And the monitor supports HL7 protocol.

**NOTE:**

- 1 Make sure the network connection between the monitor and MFM-CMS is in good condition when the time synchronization function on the monitor is active. (Default setting is off. Setting path: **Menu > Maintenance > User Maintain > Date/Time Setup > Sync Time**). If the setting is on, the monitor will accept time synchronization from MFM-CMS.
- 2 The time synchronization function might not be available to all software versions of MFM-CMS. Consult our technical service department or your local distributor for more information.
- 3 When deploying the network of the monitor and MFM-CMS, it is recommended to isolate the network and the Intranet system of the hospital by using VLAN so as to ensure the network security. Only trusted devices are allowed to join the VLAN network.
- 4 When the monitor is connected to MFM-CMS (V2.64 above) and Gateway (V1.1 above), user should turn on **Transmission Encryption** function through **User Maintain > Security > CMS/Gateway Encryption** to validate it. When the monitor is connected to MFM-CMS (V2.64 or below) and Gateway (V1.1 or below), the monitor's **CMS/Gateway Encryption** function should be turned off. To ensure security, upgrade MFM-CMS and Gateway to the latest version.

## Chapter 8 User Interface

### 8.1 Setting Interface Style

The user can set the interface based on the requirement, and the set options include the following:

- Sweep of the waveform.
- Parameters needing to be monitored.

Change to some settings may have the risk, so only the authorized person can change them. After changing the settings, please notify the operator.

### 8.2 Selecting Display Parameters

The user can select the display parameters based on the monitoring and measurement requirements. To select the parameter, please:

1. Select the shortcut key  on the shortcut widget screen directly, or
2. Select **Menu > System Setup > Module Switch**.
3. Select the required parameters from the popup interface.
4. Exit the menu and the screen will adjust the parameters automatically.

### 8.3 Changing Waveform Position

The user can exchange the waveform positions of parameter A and parameter B with the following method:

1. Select waveform A and open the setup menu of waveform A.
2. Select **Change** from the popup menu and select the desired label name of waveform B from the pull-down list.

### 8.4 Changing Interface Layout

Select **Menu > Display Setup** to open the **Display Setup** menu on which you can

- Select a function screen based on the clinical requirements by configuring **View Selection**.
- Select the maximum number of waveforms displayed on the screen by configuring **Wave Num.**.
- Decide whether the control bar is displayed or not displayed on the screen by setting **Control Bar** to **On** or **Off**.

## 8.5 Viewing Trend Screen

To view the trend screen, the user can press the shortcut key  on the shortcut widget screen or select **Menu > Display Setup > View Selection > TrendScreen**.

Select short trend to open **Short Trend Setup** menu, the user can set:

1. **Parameter**.
2. **Interval**: set the interval to **30 min, 1 h** and **2 h**.

## 8.6 Viewing OxyCRG Screen

To view the OxyCRG screen, the user can press the shortcut key  on the shortcut widget screen or select **Menu > Display Setup > View Selection > OxyCRG**. This interface is always used in NICU because the SpO<sub>2</sub>, HR and RESP of the neonate are different from those of adults. OxyCRG is in the bottom half part of wave area; it consists of HR trend, SpO<sub>2</sub> trend and RR trend or compressed respiration waveform.

Select OxyCRG waveform to open **OxyCRG Setup** menu, you can set:

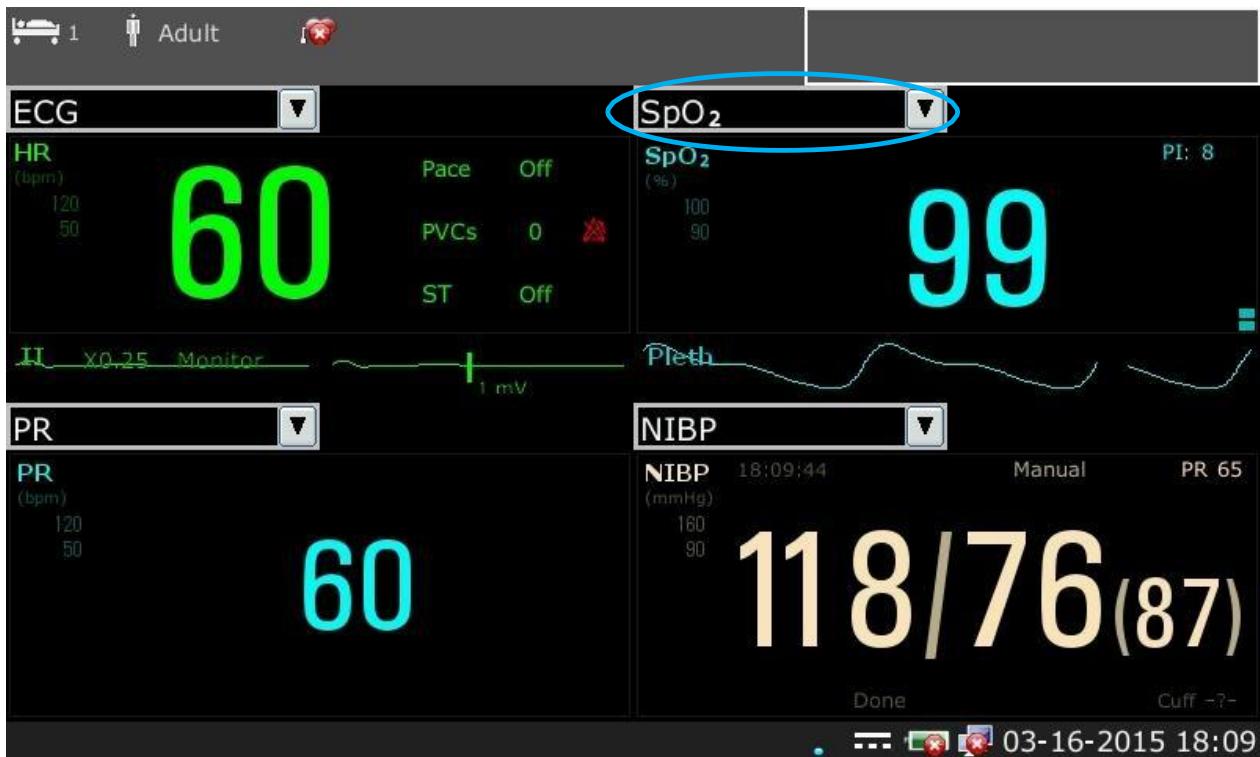
1. **Interval**: set the interval to **1 min, 2 min** and **4 min**.
2. **Parameter**: to select **RESP** or **RR**.
3. **OxyCRG Review**: user can review the 24 hours OxyCRG parameters including HR, SpO<sub>2</sub>, RR. Clicking  or  to left or right move the screen for viewing OxyCRG. Click **Exit OxyCRG Review** to exit the interface.

## 8.7 Viewing Large Font Screen

To open the large font screen, please refer to the following steps:

1. Select the shortcut key  on the shortcut widget screen or.
2. Select **Menu > Display Setup > View Selection > Large Font** to open this interface.

You can view any available parameter by selecting the parameter from the pull-down list on each section.



## 8.8 Viewing Vital Screen

To view the vital screen, the user can press the shortcut key  on the shortcut widget screen or select **Menu > Display Setup > View Selection > Vital**.

## 8.9 Changing Parameter and Waveform Colors

The user can set the display colors of parameter and waveform as desire. To change the display color, please select **Menu > Maintenance > User Maintain**, enter the required password. Then select **Color Setup** to make color changes on parameter and waveform.

## 8.10 Displaying the Timer

The monitor has the timer function to notify you when a preset time period is expired. To display the timer on the main interface,

1. Select the shortcut key  on the screen directly, or select **Menu > System Setup > Module Switch**.
2. Select **Timer** from the popup interface. Exit the menu and the screen will adjust the parameters automatically.

In the timer displaying area, the user can set the timer counting direction. Select **Timer Setup > Timing Direction**.

- **Count Down:** to display the remaining time. When the user selects **Count Down**, **Timing Duration** shall be set simultaneously. The timing duration can be set between 0 and 120 hours. Default setting is 5 min. When the remaining time is 30 seconds, the time turns red,

prompting you that the timing duration is to expire. When the timing duration expires, the monitor issues a reminder tone. To set the reminder tone volume, select **Menu > System Setup > Reminder Volume**.

- **Count Up:** to display the elapsed time.

When the **Timing Direction** is **Count Down**, the user can select **Start/Pause/Resume** or **Cancel** to start/pause/resume or end the timer; When the **Timing Direction** is **Count Up**, the user can select **Start** or **Cancel** to start or clear the timer.

To turn off the timer displaying, the user can remove the timer in the module switch menu.

**NOTE:**

- 1 The user cannot change timer settings when a timer is running.
- 2 Do not use the timer to schedule critical patient-related tasks.
- 3 The timer function is not available in privacy mode or standby mode.

## 8.11 Profile

Select **Menu > Maintenance > User Maintain > Profile**, enter the required password, users can save the current monitor's configuration, delete the saved user configuration and rename it. Three pieces of user configuration can be saved in the monitor. Users can select as desire.

To set default configuration, select **Menu > Profile**. On the **Profile** menu, users can choose a factory configuration (adult, pediatric or neonate) based on the patient category. The one labeled with ● is current configuration. If there's no labeled configuration, it means the currently used configuration is not one of them.

# Chapter 9 Monitoring ECG

## 9.1 Overview

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the monitor as a waveform and a numeric. This chapter also tells you about arrhythmia monitoring and ST monitoring.

## 9.2 ECG Safety Information

### **WARNING**

- 1 Only use the ECG leads supplied by the manufacturer when using the monitor for ECG monitoring.
- 2 When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient but not the conductive part or ground.
- 3 Place the electrode carefully and ensure a good contact. Check every day whether there is skin irritation resulted from the ECG electrodes. If yes, replace electrodes every 24 hours or change their sites.
- 4 Store the electrodes in room temperature. Open the electrode package immediately prior to use. Never mix electrode types or brands. This may lead to problem due to impedance difference. When applying the electrodes, avoid bones close to skin, obvious layers of fat and major muscles. Muscle movement can result in electrical interference. Applying electrodes on major muscles, for example on muscles of thorax, may lead to erroneous arrhythmia alarm due to excessive muscle movement.
- 5 Check if the lead connection is correct before monitoring. If you unplug the ECG cable from the socket, the screen will display the error message “ECG LEAD OFF” and the audible alarm is activated.
- 6 If the ECG signal exceeds the measuring range, the monitor will indicates it by a message “ECG Signal Exceeded”.
- 7 In order to avoid being burnt, please keep the electrodes far away from the radio knife while using electrosurgical equipment.
- 8 When using Electrosurgery (ES) equipment, do not place an electrode near the grounding plate of the Electrosurgery device, otherwise there will be a great deal of interference with the ECG signal.
- 9 The electrodes should be made of the same metal materials.
- 10 ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.

**WARNING**

- 11 According to AAMI specifications the peak of the synchronized defibrillator discharge should be delivered within 60 ms of the peak of the R wave. The synchronization pulse output on the patient monitors is delayed by a maximum of 35 ms from the R wave peak. Your biomedical engineer should verify that your ECG/Defibrillator combination does not exceed the recommended maximum delay of 60 ms.
- 12 Before outputting signals with ECG, check if the output is functioning normally.
- 13 ECG accessories are not suitable for DIRECT CARDIAC APPLICATION (Refer to IEC60601-1 for more information about the definition of DIRECT CARDIAC APPLICATION).
- 14 Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. When the electrode or lead is loose or fallen, the monitor is easily affected by the transient response of certain types of insulation monitors. The transient monitor signal produced by poor insulation of the line may be very similar to the actual heart waveform, which will prevent the monitor from prompting a heart rate alarm. In order to avoid this, user should check lead wires for damage and ensure good skin contact prior to and during use. Always use fresh electrodes and follow proper skin preparation techniques.
- 15 The monitor can only be used on one patient at a time. Monitoring more than one patient simultaneously may result in hazards to the patient.
- 16 Pacemaker Failure: During a complete cardiac block or when pacemaker is unable to pacing/capture, high P-wave (greater than 1/5 of the average height of the R-wave) may be incorrectly counted by the monitor, which leads to a missing asystole.

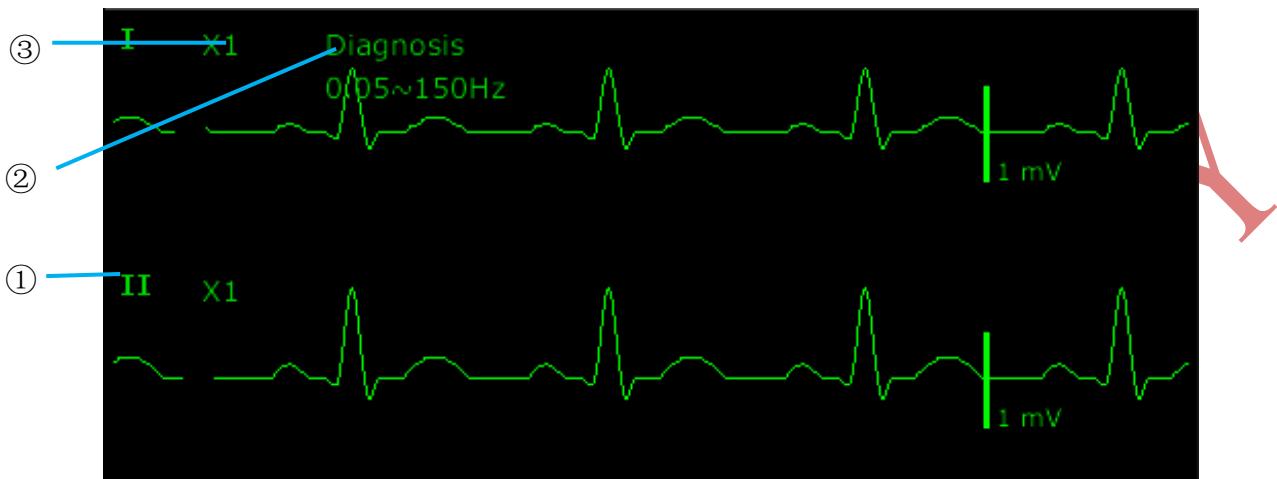
**NOTE:**

- 1 Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.
- 2 IEC/EN60601-1-2 (protection against radiation is 3 v/m) specifies that the electrical field density exceeding 3 v/m may cause measurement error in various frequencies. It is accordingly suggested that do not use equipment generating electrical radiation near ECG/RESP monitoring devices.
- 3 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.
- 4 If the pacemaker signals are beyond the claimed range, the heart rate may be calculated incorrectly.
- 5 In the default settings of the monitor, the ECG waveforms are the first two waveforms from top in the waveform area.
- 6 For measurements in or near the heart we recommend connecting the monitor to the potential equalization system.

7 For protecting environment, the used electrodes must be recycled or disposed of properly.

## 9.3 ECG Display

The figure below is for reference only.



The symbol ① indicates lead name of display waveform: there are several options, such as **I**, **II**, **III**, **aVR**, **aVF**, **aVL**, **V** (for 5 Electrodes). If you want to change the lead, please refer to Section *Selecting Calculation Lead*.

The symbol ② indicates Filter setting, there are six options: **Monitor**, **Surgery**, **Diagnosis**, **Enhanced**, **Diagnosis 1**, and **Customized**. If you want to change it, please refer to Section *Changing the ECG Filter Setting*.

The symbol ③ indicates waveform gain: there are several options, such as **X0.125**, **X0.25**, **X0.5**, **X1**, **X2**, **X4** and **AUTO**. If you want to change it, please refer to Section *Changing the Size of the ECG Wave*.

### 9.3.1 Changing the Size of the ECG Wave

If any of the displayed ECG waveform is too small or clipped, you can change the size of it on the screen. First select **ECG Waveform Setup > ECG Gain**, then select an appropriate factor from the pop-up box to adjust the ECG waveform.

**X0.125**: make the size of 1 mV ECG waveform signal become 1.25 mm;

**X0.25**: make the size of 1 mV ECG waveform signal become 2.5 mm;

**X0.5**: make the size of 1 mV ECG waveform signal become 5 mm;

**X1**: make the size of 1 mV ECG waveform signal become 10 mm;

**X2**: make the size of 1 mV ECG waveform signal become 20 mm;

**X4**: make the size of 1 mV ECG waveform signal become 40 mm;

**AUTO** let the monitor choose the optimal adjustment factor for all the ECG waves.

**NOTE:**

The effect of ECG wave gain is subject to the size of the wave area. Whichever wave gain is chosen, the ECG wave has to be displayed within the wave area, the exceeded part is clipped.

### 9.3.2 Changing the ECG Filter Settings

The ECG filter setting defines how ECG waves are smoothed. An abbreviation indicating the filter type is shown underneath the lead label on the monitor display. Filter settings do not affect ST measurement.

To change the filter setting, in the **ECG Setup** menu, select **Filter** and then select the appropriate setting.

- **Monitor:** Use this mode under normal measurement conditions.
- **Surgery:** The filter reduces interference to the signal. It should be used if the signal is distorted by high frequency or low frequency interference. High frequency interference usually results in large amplitude spikes making the ECG signal look irregular. Low frequency interference usually leads to a wandering or rough baseline. In the operating room, the Filter reduces artifacts and interference from electro-surgical units. Under normal measurement conditions, selecting **Surgery** may suppress the QRS complexes too much and thus interfere with the clinical evaluation of the ECG displayed on the monitor.
- **Diagnosis:** Use when undistorted signal is required and its own characteristics can be maintained. The waveform filtered by the bandwidth of 0.05 Hz~150 Hz is displayed so that the actual changes such as R-wave notching or discrete elevation or depression of the ST segments are visible.
- **Enhanced:** It should be used if the signal is distorted by strong interference from high frequency or low frequency. If there is still obviously interference in the signals when select surgery filter mode, it is recommended to choose the enhanced mode. In this mode, QRS wave rhythm information is emphasized, its shape information cannot be considered as diagnostic criteria. Under normal measurement conditions, the selection of this mode may inhibit QRS wave group and interfere ECG analysis.
- **Diagnosis 1:** To meet the filtering requirements of ST analysis, it is used when ST analysis is turned on or when ST analysis results are concerned.
- **Customized:** User can set **High-pass Filter** and **Low-pass Filter** as needed. Cutoff frequency of **High-pass** can be selected as: **0.01 Hz, 0.05 Hz, 0.15 Hz, 0.25 Hz, 0.32 Hz, 0.5 Hz** and **0.67 Hz**. Cutoff frequency of **Low-pass Filter** can be selected as: **25 Hz, 35 Hz, 45 Hz, 75 Hz, 100 Hz**, and **150 Hz**. After **High-pass filter** and **Low-pass Filter** are set, the bandwidth range of high – pass bandwidth to low - pass bandwidth can be formed.

## 9.4 Selecting Calculation Lead

To set the calculation lead, select **ECG Setup > Calc. Lead**, or on the **Normal** display interface, click on the calculation lead waveform area, select **Calc. Lead** from the popup interface to make the appropriate setting. For 3 Electrodes, II, I, and III are selectable; For 5 Electrodes, II, I, III,

aVR, aVL, aVF, and V are selectable; For 6 Electrodes, II, I, III, aVR, aVL, aVF and leads responding to Va and Vb are selectable; For 10 Electrodes, II, I, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6 are selectable. Normal QRS complex should be:

- The normal QRS should be either completely above or below the baseline and it should not be biphasic. For paced patients, the QRS complexes should be at least twice the height of pace pulses.
- The QRS should be tall and narrow.
- The P-waves and the T-waves should be less than 0.2 mV.

**NOTE:**

Make sure you have selected the best lead with the best waveform amplitude and highest signal-to-noise ratio. Choosing the best lead is important for heart beat test, heart beat classification and ventricular fibrillation detection.

## 9.5 Monitoring Procedure

### 9.5.1 Preparation

The skin is a poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

- Select sites with intact skin, without impairment of any kind.
- Shave hair from sites, if necessary.
- Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because this increases skin impedance).
- Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

### 9.5.2 Connecting ECG Cables

1. Attach clip or snap to electrodes prior to placement.
2. Put the electrodes on the patient. Before attaching, apply some conductive jelly on the electrodes if the electrodes are not electrolyte self-supplied.
3. Connect the electrode lead to the patient's cable.
4. Plug the patient cable into the ECG connector.

#### **CAUTION**

To protect the monitor from damage during defibrillation, for accurate ECG information and to protect against noise and other interference, use only ECG electrodes and cables specified by the manufacturer.

### 9.5.3 Selecting Electrode Type

To change the electrode type, please:

1. Select the ECG parameter area, open the **ECG Setup** menu;
2. Set **Electrode Type** to **3 Electrodes**, **5 Electrodes**, **6 Electrodes** or **10 Electrodes**, or **AUTO** based on the lead used.

### 9.5.4 Installing Electrodes

**NOTE:**

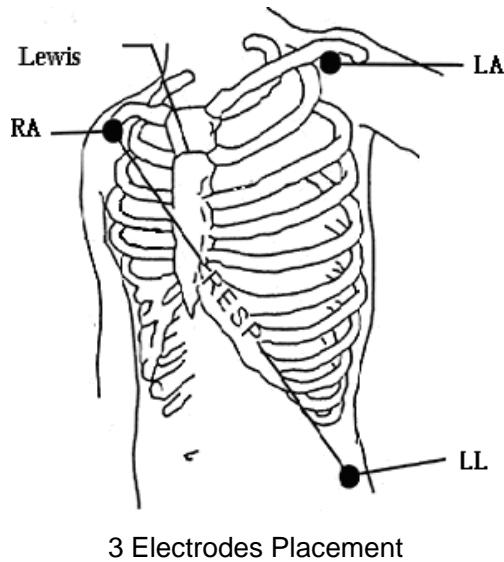
The following table gives the corresponding electrode names used in Europe and America respectively. (Electrode names are represented by R, L, F, N, C, C1-C6 in Europe, whose corresponding electrode names in America are RA, LA, LL, RL, V, V1-V6.)

AHA (American Standard)		IEC (Europe Standard)	
Electrode Labels	Color	Electrode Labels	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White
V1	Brown/ Red	C1	White/ Red
V2	Brown/ Yellow	C2	White/ Yellow
V3	Brown/ Green	C3	White/ Green
V4	Brown/ Blue	C4	White/ Brown
V5	Brown/ Orange	C5	White/ Black
V6	Brown/ Purple	C6	White/ Purple

### 3 Electrodes Placement

Take the American standard for example, see the following figure:

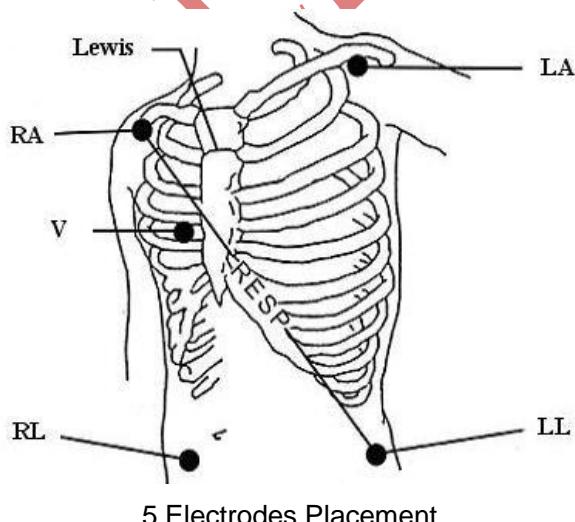
- RA placement - directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- LL placement - on the left hypogastrium.



## 5 Electrodes Placement

Take the American standard for example; see the following figure:

- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- RL placement: on the right hypogastrum.
- LL placement: on the left hypogastrum.
- V placement: on the chest, the position depends on your required electrode selection.



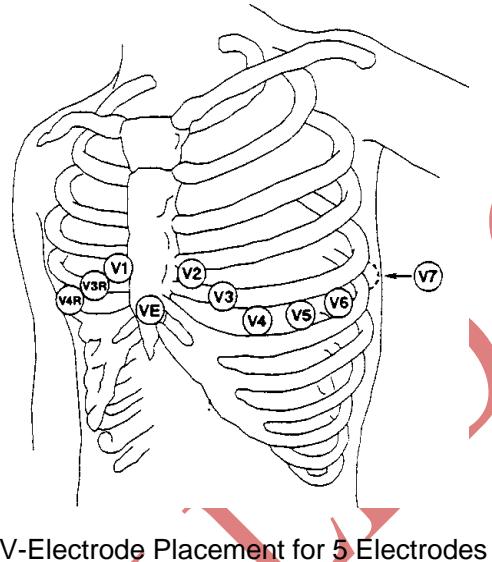
**NOTE:**

To ensure the patient safety, all electrodes must be attached to the patient.

For 5 electrodes, attach the V electrode to one of the indicated positions as below:

- V1              On the 4th intercostal space at the right sterna margin.
- V2              On the 4th intercostal space at the left sterna margin.
- V3              Midway between V2 and V4 electrodes.

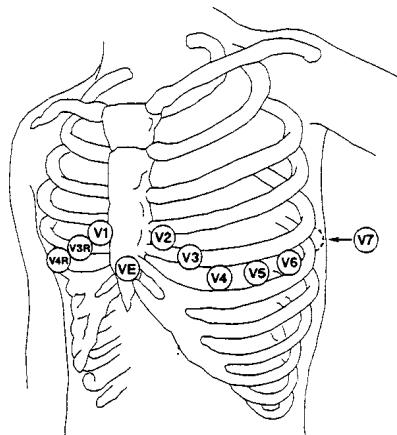
- V4              On the 5th intercostal space at the left clavicular line.
- V5              On the left anterior axillary line, horizontal with V4 electrode.
- V6              On the left middle axillary line, horizontal with V4 electrode.
- V3R-V6R        On the right side of the chest in positions corresponding to those on the left.
- VE              Over the xiphoid position.
- V7              On the 5th intercostal space at the left posterior axillary line of back.
- V7R             On the 5th intercostal space at the right posterior axillary line of back.



## 6 Electrodes Placement

For the placement of 6 electrodes, please use the position of 5 electrodes in the schematic diagram to remove the two thoracic leads. The two thoracic leads Va and Vb can be placed at anytwo positions from V1 to V6, as shown in the following thoracic leads. To ensure that the label is correct, the selected Va and Vb placements must be set simultaneously in **ECG Setup**.

- V1              On the 4th intercostal space at the right sterna margin.
- V2              On the 4th intercostal space at the left sterna margin.
- V3              Midway between V2 and V4 electrodes.
- V4              On the 5th intercostal space at the left clavicular line.
- V5              On the left anterior axillary line, horizontal with V4 electrode.
- V6              On the left middle axillary line, horizontal with V4 electrode.
- V3R-V6R        On the right side of the chest in positions corresponding to those on the left.
- VE              Over the xiphoid position.
- V7              On the 5th intercostal space at the left posterior axillary line of back.
- V7R             On the 5th intercostal space at the right posterior axillary line of back.



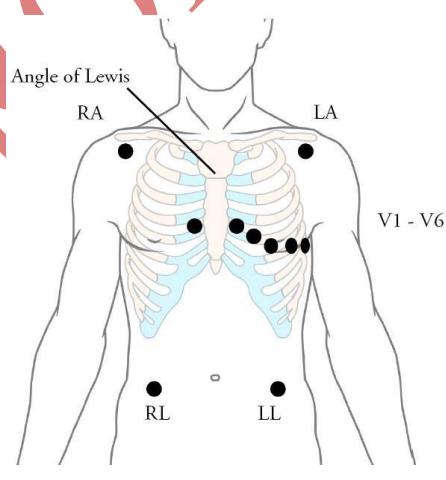
V-Electrode Placement for 6 Electrodes

## 10 Electrodes Placement

Take the American standard for example; the 10 electrodes should be placed as follows:

The limb electrodes are placed in the same position as the 3 electrodes placement.

- RL placement: on the right hypogastrium.
- V1: On the 4th intercostal space at the right sterna margin.
- V2: On the 4th intercostal space at the left sterna margin.
- V3: Midway between V2 and V4 electrodes.
- V4: On the 5th intercostal space at the left clavicular line.
- V5: On the left anterior axillary line, horizontal with V4 electrode.
- V6: On the left middle axillary line, horizontal with V4 electrode.



10 Electrodes Placement

## Recommended ECG Electrodes Placement for Surgical Patients

### **WARNING**

When using Electrosurgery (ES) equipment, leads should be placed in a position in equal distance from Electrosurgery electrotome and the ES grounding plate to avoid cautery. Electrosurgery equipment wire and ECG cable must not be tangled up.

Monitoring ECG leads are mainly used for monitoring the patient's vital signs. When using the patient monitor with other electrosurgery equipment, it is advised to use the counteracting defibrillation ECG lead.

The placement of the ECG leads will depend on the type of surgery that is being performed. For example, in an open chest surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artifacts may affect the ECG waveform due to the use of ES (Electrosurgery) equipment. To help reduce this you can place the electrodes on the right and left shoulders, the right and left sides near the abdomen, and the chest lead on the left side at mid-chest. Avoid placing the electrodes on the upper arms. Otherwise the ECG waveform will be too small. ECG cables can be damaged when connected to a patient during defibrillation or using

### **WARNING**

other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.

### **NOTE:**

- 1 If an ECG waveform is not accurate, while the electrodes are tightly attached, try to change the leads displayed on the screen.
- 2 Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

## 9.6 ECG Menu Setup

### 9.6.1 Setting Alarm Source

To change the alarm source, please select **ECG Setup > Alarm Source**, then a pop-up box is displayed:

**HR**: the monitor considers the HR as HR/PR alarm source;

**PR**: the monitor considers the PR as HR/PR alarm source;

**AUTO**: If the Alarm Source is set to **AUTO**, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and at least one ECG lead can be measured without a technical condition. The monitor will automatically switch to PR as the alarm source if:

- a valid ECG lead can no longer be measured and
- a PR source is switched on and available.

The monitor then uses the pulse rate from the measurement currently active as system pulse. While PR is the alarm source, all arrhythmia and ECG HR alarms are switched off. If an ECG lead becomes available again, the monitor automatically uses HR as alarm source.

### 9.6.2 Setting Beat Source

To change the beat source, select either **ECG Setup > Beat Source** or **PR Setup > Beat Source**. Select from the following options:

**HR**: HR is HR/PR beat source;

**PR**: PR is HR/PR beat source;

**AUTO**: If the Beat Source is set to **AUTO**, the monitor will use HR as the beat source whenever the ECG measurement is switched on, and at least one ECG lead can be measured. The monitor will automatically switch to PR as the beat source if:

- a valid ECG lead can no longer be measured and
- a PR source is switched on and available.

If an ECG lead becomes available again, the monitor automatically uses HR as beat source and the monitor gives a “Di” tone with a blinking heart  displaying in the HR parameter box when one heartbeat is detected. While a pulse is detected, the monitor gives a “Da” tone.

### 9.6.3 Smart Lead Off

When **Smart LeadOff** is set to **On**, if the current selected calculation lead can not detect ECG signal, the monitor automatically switches the corresponding lead as calculation lead, and switches the waveform display of calculation lead at the same time. When ECG electrode is re-connected, and the original calculation lead recover its signals, the monitor automatically switch to the original calculation lead.

To change the smart lead off setting, select **ECG Setup > Smart LeadOff**, and select the desired setting.

### 9.6.4 ECG Screen Layout

It varies with **Electrode Type**. When **Electrode Type** is set to **3 Electrodes**, **Screen Layout** can be set to **Normal**, and it can display one ECG waveform on the main screen.

When **Electrode Type** is set to **5 Electrodes** or **6 Electrodes**, **Screen Layout** can be set to **Normal**, **Full-Scr** and **Half-Scr**. Select **Normal** to display two ECG waveforms on the main screen; select **Full-Scr** to display seven ECG waveforms which occupy the area of seven waveforms on the main screen, to display eight ECG waveforms which occupy the area of eight waveforms on the main screen; Select **Half-Scr** to display seven ECG waveforms on the screen, occupying the area of four waveforms.

When **Electrode Type** is set to **10 Electrodes**, **Screen Layout** can be set to **Normal** and **12 Leads**. Select **Normal** to display two ECG waveforms on the main screen; select **12 Leads** to

display 13 ECG waveforms.

**NOTE:**

- 1 If **3 Electrodes** is selected in the **ECG Setup** menu, only **Normal** can be selected for **Screen Layout** in the sub-menu.
- 2 In **10 Electrodes** display interface, the filter can only be set to **Diagnosis**.
- 3 If **6 Electrodes** is selected in the **ECG Setup** menu, Va and Vb can be respectively set to either Lead V1 ~ V6, but cannot be set to the same lead, Va is Lead V2 by default, Vb is Lead V5 by default.
- 4 If **AUTO** is selected in the **ECG Setup** menu, when the electrodes connected to patient is reduced from 10 electrodes to 3/5/6 electrodes, user can click **Update Electrode** button to enable the monitor to perform lead off alarm according to actual electrodes.
- 5 If **AUTO** is selected in the **ECG Setup** menu, Va and Vb cannot be set when the monitor recognizes the 10 electrodes system automatically. Va is fixed as V1 and Vb is fixed as V2.

### 9.6.5 Setting Pace Status

It is important to set the paced status correctly when you start monitoring ECG. To change the paced status in the ECG Setup menu, select **Pace** to switch between **On** or **Off**. When **Pace** is set to **On**:

- Pace Pulse Rejection is switched on. This means that pacemaker pulses are not counted as extra QRS complexes.
- Paced symbol is displayed as | on the main screen. At this time, the artifact is displayed on the screen instead of the actual pacemaker crest. All pacemaker crests are the same, so do not give a diagnostic explanation about the size and shape of the pacemaker crest.

**NOTE:**

When monitoring a patient with a pacemaker, set **Pace** to **On**. If monitoring a patient without a pacemaker, set **Pace** to **Off**.

#### **WARNING**

- 1 Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Be sure to check the paced symbol on the displayscreen has correctly detected the pacing pulse. Keep pacemaker patients under close observation.
- 2 For patients with pacemakers, the pace must be switched ON. Otherwise, the pacing impulse may be counted as regular QRS complexes, which could prevent an asystole event from being detected. When changing settings and admitting patients, please make sure the pace mode is always correct.

**WARNING**

- 3 External pacing electrodes: When using pacemakers with external pacing electrodes on the patient, the quality of arrhythmia is severely degraded due to the high energy level in the pacemaker pulse. This can cause arrhythmia algorithms cannot detect the pacemaker without capturing or asystole.

### 9.6.6 ECG Calibration

This item is used to calibrate ECG waveform. When you select this item from ECG Setup menu again, the ECG waveform calibration ends.

**NOTE:**

The patients can't be monitored during ECG calibration.

### 9.6.7 ECG Waveform Settings

To change the speed, select **ECG Waveform Setup > Sweep**, then select an appropriate setting from the pop-up list. The bigger the value is, the wider the waveform is.

Select **ECG Waveform Setup > Cascade**: Turn on or off ECG cascade. Cascade means the ECG waveforms displayed on the screen all occupy the area of two waveforms. This function is valid only when **Screen Layout** is set to **Normal**.

## 9.7 12-Lead ECG Monitoring (Optional)

In 12-lead display mode, 12 ECG waveforms and one rhythm lead waveform will be shown at the waveform area on the screen. The rhythm lead is for ECG calculation before entering 12-lead display mode. Also, in this mode, the filter mode is set to **Diagnosis** and cannot be changed.

**NOTE:**

- 1 The 12-lead analysis results are for reference only and the clinical significance must be determined by the physician.
- 2 If the ECG signal is too weak, the 12-lead analysis results might be affected.
- 3 Regarding to the standards' instructions for ECG measurement and analysis of the monitor.
- 4 For 12-lead analysis, the gain selection contains: 1.25 mm/mV ( $\times 0.125$ ), 2.5 mm/mV ( $\times 0.25$ ), 5 mm/mV ( $\times 0.5$ ), 10 mm/mV ( $\times 1$ ), AUTO gain.
- 5 As the 12-lead analysis system of the monitor is not exactly identical to the 12 conventional ECG leads obtained from an electrocardiograph, its measurement is for reference only and should not be used for diagnostic interpretations.

### 9.7.1 Activating 12-Lead ECG Monitoring

Select **Menu > Maintenance > User Maintain > Other Setups > Activate 6/10 Electrodes** in order to get the SN number which is supposed to be supplied to the manufacturer for a

corresponding password. Enter the password on the above-mentioned interface and restart the monitor, and the 6/10 Electrodes ECG monitoring function will be activated.

#### **NOTE:**

If the 6/10 Electrodes ECG monitoring fails to be activated, users can reenter the password and try to activate this function again.

### 9.7.2 Analysis Function

If your monitor is configured with the 12-lead ECG monitoring function, the monitor can perform automatic analysis function. To perform 12-lead analysis:

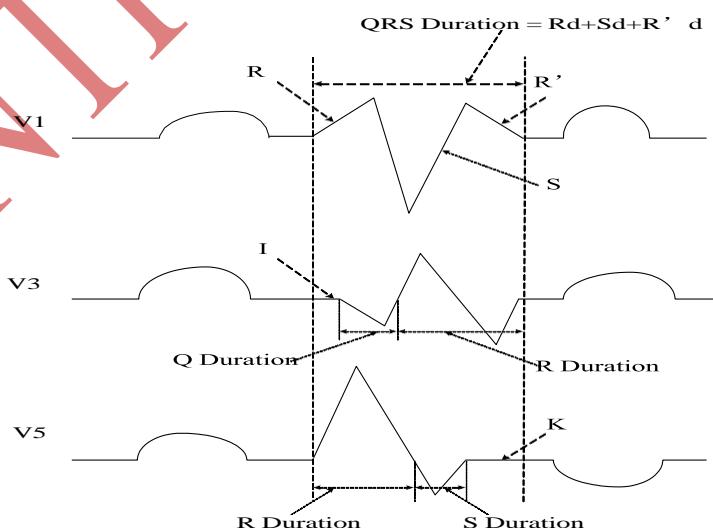
1. In the **ECG Setup** menu, set **Electrode Type** to **10 Electrodes** and set **Screen Layout** to **12 Leads**.
2. Select the shortcut key  on the shortcut widget screen directly.
3. The analysis results will be provided in the **Analysis Review** window after approximately 10 seconds.

The measurement function provides the automatic measurement of the common parameters, such as heart rate, PR interval, QRS duration, QT/QTC interval, P/QRS/T axis, RV5/SV1 amplitude and RV5+SV1 amplitude. The interpretation function provides the automatic analysis of hundreds of abnormal cases, such as arrhythmia, AV block, IVCD (Intraventricular Conduction Block), myocardial infarction, ventricular hypertrophy and atrial enlargement, ST-T abnormality and electrical axis deviation.

### 9.7.3 Waveform Durations and Isoelectric Segments

Between the global onset and offset of the QRS-complex, signal parts with a duration of more than 6 ms and amplitude not exceeding 20  $\mu$ V should be defined as isoelectric segments.

Because the duration of the Q-, R- or S-wave of 12 leads is respectively detected by the ECG algorithm, isoelectric parts (I-waves) after global QRS-onset or before global QRS-offset (K-wave) are excluded in the measurement duration of the respective adjacent waveform.



## 9.8 ST Segment Monitoring

The monitor performs ST segment analysis on normal and atrially paced beats and calculates ST segment elevations and depressions. This information can be displayed in the form of ST numerics and ST templates on the monitor.

ST segment monitoring function is shut off by default. You can switch it to **On** when necessary. When using the ST analysis function, the ST analysis results will be displayed on the right of the main screen.

### NOTE:

- 1 ST-segment analysis is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients. For this reason, the recommended and default setting for ST analysis in neonatal and pediatric modes is **Off**.
- 2 In ST analysis, the obtained ST value and ST template are all unaffected by the selected filter mode. ST algorithm itself uses a dedicated linear filter to ensure the signal is not distorted, and to better ensure the consistent and accurate measurement value and ST template can be obtained in different filter modes. If the doctor wants to observe the waveform to evaluate ST segment result, it is recommended to use the ST template for observation, as it is not affected by the filtermode. If the real-time waveform displayed on the interface is used to evaluate ST segment result, it is recommended to select **Diagnosis** mode.
- 3 Reliable ST monitoring may be influenced in following situations:
  - You are unable to get a lead with low noise
  - If there is arrhythmia such as atrial fibrillation/flutter, the ECG baseline may be irregular.
  - The patient is continually performing ventricular paced.
  - The patient cannot get the leading template for a long time.
  - The patient has left bundle branch block.When any of above situations happens, ST monitoring should be switched off.
- 4 The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.
- 5 If you use ST analysis, you must adjust the ST measurement point when you start the monitor. If the patient's heart rate or ECG waveform changes significantly, this will affect the size of the QT interval, so the ST point must be placed. If the equipotential or ST points are not set correctly, the ST fragments of the artifacts maybe depressed or raised. Always ensure that the ST measurement point is suitable for your patient.
- 6 ST values may be affected by such factors as some drugs or metabolic and conduction disturbances.
- 7 ST is calculated with a fixed delay from the R position. Changes in heart rate or the

- width of QRS may affect ST.
- 8 If the algorithm triggers self-learning (either manually or automatically), the calculation of ST segment will be reinitialized.

### 9.8.1 Setting ST Analysis

To change ST analysis, please select **ECG Setup > ST Analysis**, then select **On** or **Off** from the pop-up list.

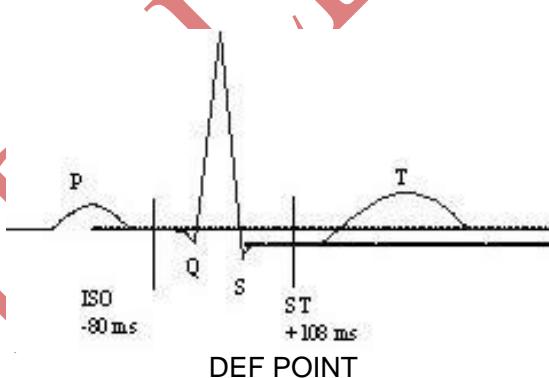
### 9.8.2 ST Display

Your monitor screen may be configured to look slightly different from the illustrations.

<b>ST</b>	<b>I</b>	<b>0.08</b>	<b>aVR</b>	<b>-0.09</b>	<b>V</b>	<b>0.04</b>
	<b>II</b>	<b>0.10</b>	<b>aVL</b>	<b>0.03</b>		
	<b>III</b>	<b>0.02</b>	<b>aVF</b>	<b>0.06</b>		

### 9.8.3 About ST Measurement Points

The ST value for each beat complex is the vertical difference between the ISO point and the ST point, as shown in the diagram below. The isoelectric (ISO) point provides the baseline, and the ST point is at the midpoint of the ST segment. The J point is where the QRS complex changes its slope; as it is a fixed distance away from the ST point, it can be useful to help you position the ST point correctly.



The ST and ISO measurement points need to be adjusted when you start monitoring, and if the patient's heart rate or ECG morphology changes significantly. Always ensure that ST measurement points are appropriate for your patient. Abnormal QRS complex is not considered in ST segment analysis.

### 9.8.4 Adjusting ST and ISO Measurement Points

Depending on your monitor's configuration, the ST point can be positioned, too.

These two points can be adjusted by moving the cursor line. When adjusting ST measurement point, the system will show the ST Measurement Point Window. The system displays the QRS complex template in the window. It is adjustable for the highlight bar in the window. You may select ISO or ST, move the cursor line left or right. When the cursor is at the required position,

you may select the base point or the measurement point.

### 9.8.5 ST Alarm Setup

Select **ECG Setup > ST Analysis > ST Alarm Setup** to change the ST Alarm Mode:

**Real Time:** The user can set the alarm switch, alarm level, alarm limit and alarm record separately for each ST or all ST.

**Differential:** The monitor triggers the alarm according to the change of ST. The user does not need to set alarm for each ST separately, but only need to set alarm switch, alarm level and alarm difference value (-0.1~0.1) for all ST.

When **ST Alarm Mode** is differential, the user needs to select **Delay** to set the ST alarm delay time. **3 seconds** and **5 seconds** are optional, and the default is **3 seconds**. Besides, the Difference and baseline value shall be set, the difference range is 0.01 mv ~0.1 mv, and the baseline range is -1.90 mv ~1.90 mv.

### 9.8.6 ST View

The ST View displays a complete QRS segment for each ST lead. The color of current ST segment and ST value are consistent with the color of HR. The color of baseline and ST value are yellow. To enter ST view, please select **ST View** in **ST Analysis**.

In the ST View interface, the user can save ST baseline through clicking **Save as Base** when ST values gets stable. If no ST baseline is saved, the monitor automatically saves the baseline when the first valid and complete ST waveform appears.

In the ST View interface, the user can display the current waveform, baseline waveform, or the both by selecting **Real**, **Baseline** or **Real+Base**. The user can also hide or display ST points by selecting **Hide Points** or **Show Points**. Besides, the user can record and print the ST view.

In the ST View interface, the user can save ST segment through clicking **Save ST SEG**. Up to 20 groups of ST segments can be saved. When the 21<sup>st</sup> ST segment is saved, the earliest ST segment will be deleted.

#### NOTE:

The ST baseline and ST segment will be cleared in following situations:

- 1) Turning off the monitor;
- 2) Changing the electrode type;
- 3) Changing the calculation lead in 3 electrodes;
- 4) Entering or exiting Demo mode;
- 5) Changing the patient type;
- 6) Admitting new patients;

In order to view the ST value situation of each lead more intuitively, the user can enter into the ST Histogram. The horizontal axis shows the lead name while the vertical axis shows the ST value. And the bar graph is used to display the ST value result. The ST histogram refreshes with ST View synchronizely.

## 9.9 Arrhythmia Monitoring

### 9.9.1 Arrhythmia Analysis

The arrhythmia algorithm is used to monitor ECG of adult patients in clinics, and detect the changes of heart rate and ventricular rhythm, and also save arrhythmia events and generate alarm information. The arrhythmia analysis is not clinically validated for use with neonatal and pediatric patients. Arrhythmia algorithm can monitor paced and non-paced patients. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and decide the treatment. Besides detecting change of ECG, arrhythmia algorithm can also monitor patients and give proper alarm for arrhythmia.

The monitor can support 2 configurations for ARR analysis, basic ARR or advanced ARR (also called Basic or Advanced). The default is advanced ARR. For configuration selection, please contact service personnel of the manufacturer.

**NOTE:**

- 1 Advanced ARR is not available in USA.
- 2 When PM PRO-2 (as sub-monitor) is connected to PM PRO-1, if PM PRO-2 supports advanced ARR, it will synchronize with PM PRO-1 monitor; if not, basic ARR will be adopted.
- 3 The measured **PVCs** and **Pause/min** will be displayed in main interface. **Pause/min** is only applicable to advanced ARR.
- 4 Advanced ARR is intended to be used with CMS 2.65 or above version.

ARR Alarms	Occurring Condition
Applicable to both basic and advanced ARR	
<b>Asystole</b>	No QRS is detected for 4 consecutive seconds
<b>V-Fib/V-Tach</b>	4 consecutive seconds' fibrillation wave occurs; Or 5 consecutive ventricular beats, and ventricular HR $\geq 100$ bpm.
<b>Couplet</b>	2 consecutive PVCs
<b>Run PVCs</b>	$3 \leq$ the number of consecutive PVCs $< 5$
<b>PVC Bigeminy</b>	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.
<b>PVC Trigeminy</b>	A dominant rhythm of N, N, V, N, N, V
<b>R on T</b>	A type of single PVC under the condition that HR<100, R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).
<b>PVC</b>	Single PVC detected in normal heartbeats, and the number of consecutive single PVC $\geq 4$ within 30 s.

ARR Alarms	Occurring Condition
<b>Tachy</b>	Adult: RR interval for 5 consecutive QRS complex $\leq 0.5$ s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\leq 0.375$ s.
<b>Brady</b>	Adult: RR interval for 5 consecutive QRS complex $\geq 1.5$ s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\geq 1$ s.
<b>Missed Beat</b>	Basic: If HR $< 120$ bpm, no beats are detected for 1.75 times average RR interval; or if HR $\geq 120$ bpm, no beats are detected for one second; or no valid QRS wave is detected within 3 s or longer.  Advanced: If HR $< 120$ bpm, no beats are detected for 1.75 times average RR interval; or if HR $\geq 120$ bpm, no beats are detected for one second.
<b>Irr Rhythm</b>	Consistently irregular heart rhythm
<b>Pacer not Capture</b>	No QRS complex detected in 300 ms after a pace pulse.
<b>Pacer not Pacing</b>	No pace pulse detected in 1.75 times RR interval after a QRS complex.
<b>Vent Brady</b>	Basic: 5 consecutive ventricular beats, and ventricular HR $< 40$ bpm.  Advanced: 5 consecutive ventricular beats, and ventricular HR $< 20$ bpm.
<b>Vent Rhythm</b>	Basic: 5 consecutive ventricular beats, and $40 \text{ bpm} \leq \text{ventricular HR} < 100$ bpm.  Advanced: 5 consecutive ventricular beats, and $20 \text{ bpm} \leq \text{ventricular HR} < 40$ bpm.
<b>PVCs High</b>	The measurement value of PVCs is greater than high alarm limit that has been set.
Applicable to advanced ARR	
<b>Sustain VT</b>	The duration of ventricular tachycardia rhythm $\geq$ the threshold value that has been set.
<b>ExtremeTachy</b>	HR $\geq$ Extreme Tachycardia threshold value that has been set.
<b>ExtremeBrady</b>	HR $\leq$ Extreme Bradycardia threshold value that has been set.
<b>V-Tach</b>	5 consecutive ventricular beats and ventricular HR $\geq 100$ bpm.
<b>Wide QRS Tachy</b>	Meet tachycardia conditions, and QRS wave width $\geq 160$ ms.
<b>Non-Sustain VT</b>	$3 \leq$ The number of consecutive ventricular beats $< 5$ , and ventricular HR $\geq 100$ bpm.

ARR Alarms	Occurring Condition
<b>Afib</b>	Atrial fibrillation alarm should meet below two conditions for 1 minute: the RR interval of normal beats must be irregular, and it can be seen that the obvious f or P waves do not exist.
<b>Acc. Vent Rhythm</b>	5 consecutive ventricular beats, and $40 \text{ bpm} \leq \text{ventricular HR} < 100 \text{ bpm}$ .
<b>Pause</b>	No QRS is detected within the heartbeat pause threshold value that has been set.
<b>Pauses/min High</b>	The measurement value of Pause/min is greater than high alarm limit that has been set.
<b>VEB</b>	The delayed ventricular beats detected in normal heartbeats occur more than or equal to 2 times within 30 s.
<b>Multiform PVCs</b>	Different forms of ventricular premature beats are detected in 15 beats.
<b>IPVC</b>	The single ventricular premature beat between 2 sinus beats with normal interval occurs more than or equal to 3 times within 30 s.
<b>PAC Bigeminy</b>	The dominant rhythm of N, A, N, A, N, A, and the rhythm number exceeds the number of threshold value that has been set (N = supraventricular beat, A = atrial beat).
<b>PAC Trigeminy</b>	The dominant rhythm of N, N, A, N, N, A, N, N, A, and the rhythm number exceeds the number of threshold value that has been set.
<b>Low Voltage(Limb)</b>	The signal amplitudes of I, II and III leads shall not exceed alarm threshold value that has been set. PS: this alarm is available for 5, 6 or 10 electrodes only, not available for 3 electrodes.
NOTE: Arrhythmia monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients. For this reason, the recommended setting for arrhythmia monitoring in neonatal and pediatric modes is Off.	

Selecting an ECG lead for Arrhythmia:

In arrhythmia monitoring, it is important to select the appropriate lead.

For non-paced patients, the guidelines are:

- QRS should be tall and narrow (recommended amplitude  $> 0.5 \text{ mV}$ )
- R wave should be above or below the baseline (but not biphasic)
- T wave should be smaller than 1/3 of the R wave height
- P wave should be smaller than 1/5 of the R wave height.

For paced patients, in addition to above guidelines, the pacemaker signal should also:

- not wider than normal QRS
- The QRS complexes should be at least twice the height of the pacing pulse
- large enough to be detected, without repolarization signal

According to Standard ISO60601-2-27, the minimum detection level of the QRS complex is set to 0.15 mV, to prevent the detection of P-wave or baseline noise as QRS complexes. Adjusting ECG displayed waveform size (gain adjustment) won't influence ECG signals which are used for arrhythmia analysis. If the ECG signal is too small, a false asystole alarm may occur.

#### Aberrantly-Conducted Beats:

As not recognizing the P waves, the monitoring system is difficult to distinguish between aberrantly-conducted beats and ventricular heartbeat. If the aberrantly-conducted beat is similar to ventricular tachycardia, it may be classified as ventricular. Make sure to select such a lead, the aberrantly-conducted beats have an R wave that is as narrow as possible to minimize the incorrect calls. The ventricular should have a different appearance from "normal heartbeat". Physicians should be more alert to these patients.

Intermittent bundle branch block: bundle branch block or other bundle obstruction phenomenon is a challenge for arrhythmia algorithm. If the QRS wave during the block has a considerable change in morphology compared to the normal QRS of learning, the blocked heartbeat may be misclassified as ventricular tachycardia, resulting in an incorrect chamber alarm. Make sure to select such a lead, which blocks the heartbeat of the R wave as narrow as possible to minimize the wrong classification. Ventricular heartbeat should have a different appearance from "normal heartbeat". Physicians should be more alert to these patients.

#### NOTE:

- 1 Heart rate reading may be affected by cardiac arrhythmias. Do not rely entirely on heart rate alarms when monitoring patients with arrhythmia. Always keep these patients under close surveillance.
- 2 Since the arrhythmia detection algorithm sensitivity and specificity is less than 100%, sometimes there may be some false arrhythmias detected and also some true arrhythmia events may not be detected. This is especially true when the signal is noisy.
- 3 The ventricular HR mentioned above refers to:
  - In basic ARR, when the consecutive PVCs number  $\geq 5$ , the algorithm calculates ventricular HR with the average of 4-8 RR intervals.
  - In advanced ARR, when the consecutive PVCs number  $\geq 3$ , the algorithm calculates ventricular HR with the average of 2-8 RR intervals.

The methods are different from the HR Averaging Method of the monitor. Therefore, the ventricular HR values calculated by basic/advanced ARR algorithm may be different from the HR values calculated by HR Averaging Method. The ventricular HR is for judging arrhythmias and is not exactly equal to the HR displayed on the interface.

- 4 The ARR analysis results and HR values obtained during ARR analysis and HR calculation are not affected by the selected filter mode. The algorithm itself has independent data-flow processing, which can better ensure the consistent and accurate results in different filter modes.
- 5 Atrial fibrillation alarm should meet below two conditions for 1 minute:

- The RR interval of normal beats must be irregular,
  - It can be seen that the obvious f or P waves do not exist.
- 6 Atrial fibrillation analysis is only applicable to adult patients and should not be performed for PVC or pacing fluctuations.
- 7 Atrial flutter cannot be detected by the atrial fibrillation algorithm because most of their RR intervals are regular.
- 8 In following situations, atrial fibrillation alarm detection error may occur:
- Sinus arrhythmia
  - Atrioventricular block
  - Frequent ventricular premature beats
  - Myoelectric interference
  - Electrode motion artifact

## 9.9.2 ARR Analysis Menu

### 9.9.2.1 Switching ARR Analysis On and Off

To switch ARR Analysis on or off, in the **ECG Setup** menu, select **ARR Analysis** to switch between **On** and **Off** from the popup interface.

### 9.9.2.2 ARR Alarm Setup

Select **ECG Setup > ARR Analysis > ARR Alarm Setup** to change the following ARR alarm settings:

- Separately switch on or off each arrhythmia alarm and set the alarm level.
- Select **All Alarms On/All Alarms Off** to switch on or off all arrhythmia alarms except key ARR alarms.
- Set the threshold of certain arrhythmia alarms. When an arrhythmia exceeds its threshold, an alarm will be triggered.
- Select **Default** to restore the ARR alarm settings to factory defaults.

Confirm the changes to make the settings effective.

**V-Fib/V-Tach, ExtremeTachy, ExtremeBrady, V-Tach and Vent Brady** are key ARR alarms and they are preset to be on. The user can switch on/off those key ARR alarms only when **Key ARR Alarm Switch Authority** is enabled. To enable the authority,

1. Select **Menu > Maintenance > User Maintain**, and enter the required password.
2. Select **Alarm Setup** and set **Key ARR Alarm Switch Authority** to **On**. If any of key ARR alarms is switched off, the bottom information area will prompt **Key ARR Alarm Off**. Clicking the prompts can view the details.

**Asystole** and **Sustain VT** alarms are preset to **On** and cannot be turned off.

**WARNING**

When the ARR alarm is set to **Off**, the monitor won't give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient's life, the user should use this function cautiously.

**NOTE:**

**Pacer not Capture** and **Pacer not Pacing** alarms are available only when **Pace** is set to **On**.

### 9.9.2.3 Adjustable Range of ARR Alarm Threshold

ARR Alarm	Range
PVCs High	1/min to 99/min
Pauses/min High	1/min to 20/min
Pause	2 s, 2.5 s, 3 s
Sustain VT	15 s to 45 s
ExtremeTachy	Adult: 120 bpm to 300 bpm; Pediatric/neonatal: 120 bpm to 350 bpm
ExtremeBrady	15 bpm to 60 bpm
PAC Bigeminy PAC Trigeminy	3/min to 50/min
Low Voltage(Limb)	0.3 mV to 0.8 mV

### 9.9.2.4 ARR Selflearning

Pick this item **ARR Selflearn** to start a learning procedure, and **ECG ARR Learning** is displayed on the screen.

The ARR selflearning will start automatically in the following status:

- Switching the ARR Analysis from Off to On;
- Changing patient type or electrodes type;
- Connecting or switching calculation leads;
- Changing pacemaker status;
- Exiting DEMO or Standby mode;
- Admitting a patient;
- Switching calibration mode into normal measurement mode;
- Switching the ECG parameter on;
- Changing-over between basic ARR and advanced ARR.

**NOTE:**

- 1 During the relearning phase of the algorithm, arrhythmia detection may not be available. So you should closely monitor the patient condition during and for several minutes after the learning phase to allow the algorithm to reach optimal detection performance.
- 2 Take care to initiate ARR selflearning only during periods of predominantly normal rhythm and when ECG signal is relatively noise-free. If ARR selflearning takes place during arrhythmia, the ectopics may be incorrectly learned as normal QRS complex. This may result in missed detection of subsequent events of arrhythmia.
- 3 If ARR selflearning is performed during ventricular rhythm, ventricular heartbeats may be erroneously identified as normal QRS complexes. This may lead to missed ventricular tachycardia and ventricular fibrillation events.

Due to this reason, you should:

- 1) Take care that ARR selflearning may start automatically;
- 2) Response to lead off information;
- 3) Always check the correctness of arrhythmia alarm.

## 9.10 QT Analysis\*

\*Not available in U.S.A.

The QT interval is the time from the beginning of Q wave to the end of T wave. It measured the total duration of the depolarization (QRS duration) and repolarization (ST-T) phases of ventricular action potential. QT analysis can help detect extended QT interval syndrome.

### 9.10.1 Measurement Limitations

The following clinical status of the patient may affect the QT analysis, and the inaccurate measurement may but is not limited to the following reasons:

- The T-wave is very flat
- Atrial flutter and atrial fibrillation make T wave is difficult to define
- The end of the T-wave is difficult to define because of the presence of U-waves
- A high heart rate causes the P-wave to encroach on the end of the previous T-wave
- Noise or the QRS wave variation is too big

In these cases, the user should choose a lead with good T wave amplitude and no visible oscillations, and without a dominant U wave or P wave.

In some conditions, such as left or right bundle branch block or cardiac hypertrophy causes broaden QRS complex. If long QTc is observed, verify it to ensure that it is not caused by QRS broadening.

Since normal beats followed by ventricular beats are not included in the analysis, QT measurement could not be carried out when there was bigeminy rhythm.

When the heart rate changes, it may take several minutes for the QT interval to stabilize. In order

to obtain reliable QTc calculations, it is important to avoid areas where the heart rate changes.

#### **NOTE:**

QT/QTc measurements should always be validated by a qualified clinician.

#### 9.10.2 Switching QT Analysis On and Off

To switch QT Analysis on or off, in the **ECG Setup** menu, select **QT Analysis** to toggle between **On** and **Off** from the popup interface.

#### 9.10.3 QT Display

The following figure is QT display for your reference only. The graphics on your monitor may be slightly different.



#### 9.10.4 Selecting QT Analysis Lead

There are two modes for selection:

All lead: Use all available leads (except pressurized the limb lead) to produce an overall QT measurement, user can select **ALL** through **ECG Setup > QT Analysis > Analysis Lead**.

Single lead: QT measurements were performed using all available single leads (except the pressurized limb lead). User selects any lead in **Analysis Lead** menu to enter into single lead mode.

#### 9.10.5 Selecting Calculation Formula

The monitor uses Bazett formula to correct QT values by default. There are four alternative formulas: **Bazett**, **Fridericia**, **Framingham** and **Hodges**.

$$\text{Hodges: } \text{QTc} = \text{QT} + 1.75 \times (\text{HR} - 60)$$

$$\text{Bazett: } \text{QTc} = \text{QT} \times \left( \frac{\text{HR}}{60} \right)^{\frac{1}{2}}$$

$$\text{Fridericia: } \text{QTc} = \text{QT} \times \left( \frac{\text{HR}}{60} \right)^{\frac{1}{3}}$$

$$\text{Framingham: } \text{QTc} = \text{QT} + 154 \times \left( 1 - \frac{60}{\text{HR}} \right)$$

#### 9.10.6 Setting QT Baseline

To quantitatively express the QTc values change, the user can set a QTc baseline, the baseline is used for calculating ΔQTc value. The user can set the baseline through **ECG Setup > QT Analysis > Save Baseline**, and the monitor displays **The Baseline is saved at:** (Time). If no baseline has been set, the first five minute QTc value after the QT measurement begins will be automatically

set as the baseline. If a new baseline is set, the previous baseline is discarded.

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Because  $\Delta QTc$  alarm is based on the difference of the baseline with the current values, inappropriate baseline settings may lead that no  $\Delta QTc$  alarm is generated.

**NOTE:**

The QT baseline will be cleared in following situations:

- 1) Turning off the monitor;
- 2) Changing the electrode type;
- 3) Changing the calculation lead in 3 electrodes;
- 4) Changing the patient type;
- 5) Admitting new patients;
- 6) Enters or exits Demo mode.

If QT analysis is needed, please reset the baseline.

#### 9.10.7 QTc Alarm Setup

Select **ECG Setup > QT Analysis > Alarm Setup** to change the following QT alarm settings:

- Separately switch on or off QTc alarm and  $\Delta QTc$  alarm and set the alarm level.
- Set the thresholds of QTc alarm and  $\Delta QTc$  alarm. When QTc value or  $\Delta QTc$  value exceeds the preset thresholds, an alarm will be triggered.

#### 9.10.8 QT View

To enter QT view, please select **ECG Setup > QT Analysis > QT View**. In the QT View interface, the color of current QT segment and QT value are consistent with the color of HR. The color of baseline and QT value are yellow.

In the QT View interface, the user can save QT baseline through clicking **Save as Base** when QT values gets stable. If no QT baseline is saved, the monitor automatically saves the baseline when the first five minutes value appears. Besides, the user can record and print the QT view.

# Chapter 10 Monitoring RESP

## 10.1 Overview

The monitor measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

## 10.2 RESP Safety Information

### **WARNING**

- 1 If you do not set the **Hold High** and **Hold Low** for the respiration correctly in manual detection mode, it may not be possible for the monitor to detect apnea. If you set the **Hold High** and **Hold Low** too low, the monitor is more likely to detect cardiac activity, and to falsely interpret cardiac activity as respiratory activity in the case of apnea.
- 2 Respiration measurements cannot detect all underexposure sudden events, nor can they distinguish between central, obstructive and mixed respiratory asphyxial events. It only prompts alarm in a predetermined time if the last breath is detected and the next breath is not detected, so it cannot be used for diagnostic purposes.
- 3 If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3 V/m), field strengths above 3 V/m may cause erroneous measurements at various frequencies. Therefore it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.
- 4 Cardiogenic artifact in impedance respiration monitoring may make it difficult to detect breaths or may otherwise be counted as breaths. In some instances, the breath rate may also correspond to the heart rate making it difficult to determine if the signal is due to breathing or the cardiac cycle. Do not rely on RESP monitoring as the sole method for detecting cessation of breathing. Follow hospital guidelines and best clinical practices for apnea detection including monitoring additional parameters that indicate the patient's oxygenation status, such as EtCO<sub>2</sub> and SpO<sub>2</sub>.
- 5 For the diagnosis of apnea, especially in premature infants and infants, the safety and effectiveness of respiration measurements have not been validated.
- 6 To monitor the respiration, only non-ESU-proof accessories can be used. This is because the internal impedance of the ESU-proof accessories required to be used for electrosurgical operation is too large.
- 7 Some implantable pacemakers can adjust their triggering frequency according to the "minute ventilation rate". Impedance respiration measurements may cause these pacemakers to react incorrectly. To prevent this, turn off the respiration measurement.

**WARNING**

- 8 In manual detection mode, after changing the gain of the respiration wave, be sure to check the setting of hold high and hold low.
- 9 When ECG electrode is placed on patient's limb, the impedance respiration may be unreliable.
- 10 Respiration measurement cannot be performed when ESU is used.

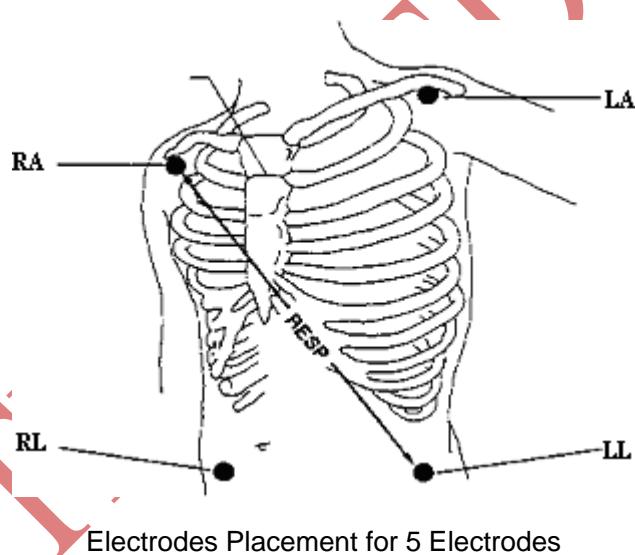
**NOTE:**

The RESP monitoring is not recommended to be used on patients who are very active, as this can cause false alarms.

### 10.3 Electrode Placement for Monitoring RESP

Correct patient skin preparation techniques for electrode placement are important for RESP measurement: you will find this information in the chapter on ECG.

The RESP signal is always measured between two of the ECG electrodes. There are two standard ECG leads for selection: I lead (RA and LA) and II lead (RA and LL).



### 10.4 Cardiac Overlay

Cardiac activity that affects the RESP waveform is called cardiac overlay. It happens when the RESP electrodes pick up impedance changes caused by the rhythmic blood flow. Correct electrode placement can help to reduce cardiac overlay: avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes. This is particularly important for neonates.

## 10.5 Chest Expansion

Some patients, especially neonates, expand their chests laterally. In these cases it is best to place the two respiratory electrodes in the right midaxillary and left lateral chest areas at the patient's maximum point of breathing movement to optimize the respiratory wave.

## 10.6 Abdominal Breathing

Some patients with restricted chest movement breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.

### NOTE:

Place the red and green electrodes diagonally to optimize the respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes so as to avoid cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.

## 10.7 Selecting RESP Lead

To change RESP lead, in the **RESP Setup** menu, select **RESP Lead** to pick up the appropriate lead from the pop-up list.

## 10.8 Changing Hold Type

To change the calculation mode, in the **RESP Setup** menu, set **Hold Type** to **Manual** or **AUTO**. When it is set to the **AUTO** mode, **Hold High** and **Hold Low** are unavailable, and the monitor can calculate the respiration rate automatically. When it is set to the **Manual** mode, you can adjust the broken lines in RESP area by the **Hold High** and **Hold Low** items.

## 10.9 Changing the Size and Speed of the Respiration Wave

Select the RESP waveform area to open the **RESP Waveform Setup** menu:

- Select **AMP**, and choose an appropriate value. The bigger the value is, the higher the waveform amplitude will be.
- Select **Sweep**: select an appropriate setting from the pop-up list.

## 10.10 Changing the Apnea Alarm Time

The apnea alarm is a high priority red alarm used to detect apneas. The apnea alarm delay time defines the time period between the point where the monitor cannot detect any respiration activity and the indication of the apnea alarm. Users should set it cautiously.

1. In the **RESP Setup** menu, select **Apnea Alm**.
2. Select the appropriate setting from the popup list.

# Chapter 11 Monitoring SpO<sub>2</sub>

## 11.1 Overview

SpO<sub>2</sub> is used to measure arterial blood oxygen saturation, which is the percentage of oxyhemoglobin in the arterial blood. SpO<sub>2</sub> parameter can also provide pulse rate (PR) and a plethysmogram wave (Pleth).

## 11.2 SpO<sub>2</sub> Safety Information

### **WARNING**

- 1 Do not use the SpO<sub>2</sub> sensors if the packaging or the sensor is damaged and return them to the vendor.
- 2 If the SpO<sub>2</sub> sensor cannot work properly, please reconnect the sensor or change a new one.
- 3 Correct and proper sensor application: if the sensor is too loose, it might compromise the optical alignment, and even cause the sensor to fall off. If the sensor is too tight, (such as the application site is too large or becomes too large due to edema), excessive pressure and local tissue ischemia, hypoxia and lack of nutrition may occur on the application site. Prolonged and continuous monitoring may increase the risk of Skin irritations or lacerations. To avoid these damages, users should periodically check surrounding skin of application site according to the patient's condition and pressure sensor, inspect the if there is sign of stress-related damage in surrounding tissue, and regularly change the application site. For the patients whose fluid is easy to transfer and/or the patients with systemic or localized edema, users should inspect the skin and change application site more frequently.
- 4 Use only sensors and extension cables permitted by the manufacturer with the monitor. Other sensors or extension cables may cause improper monitor performance and/or minor personal injury.
- 5 High oxygen levels may predispose a premature infant to retrosternal fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the high limit alarm off.
- 6 When serious arrhythmia is present, the SpO<sub>2</sub> pulse rate may differ from ECG heart rate but this does not indicate an inaccurate PR (SpO<sub>2</sub>) value.
- 7 Misapplied sensor or sensor that becomes partially dislodged may cause either over or under reading of actual arterial oxygen saturation.

### **NOTE:**

- 1 Avoid placing the sensor on extremities with an arterial catheter, intravascular venous infusion line, or inflated NIBP cuff. When measuring SpO<sub>2</sub> on the limb with inflated NIBP cuff, please turn on the **NIBP Simul** function.

- 2 When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient's condition.
- 3 If the surrounding temperature increases, the operator should pay attention to the site of poor perfusion, and increase the frequency of checking the skin and changing the measurement site to prevent burns. If the initial skin temperature is less than 35°C, the temperature of all the listed sensors on the skin will not exceed 41°C during working.
- 4 SpO<sub>2</sub> waveform is not directly proportional to the pulse volume.
- 5 The device is calibrated to display functional oxygen saturation.
- 6 A Functional tester or simulator cannot be used to assess the SpO<sub>2</sub> accuracy. However, it can be used to demonstrate that a particular monitor reproduces a calibration curve that has been independently demonstrated to meet a particular accuracy.
- 7 The cumulative use time for the SpO<sub>2</sub> sensor in a single patient should be less than 30 days.

### 11.3 Measuring SpO<sub>2</sub>

1. Select the correct patient category setting (adult/pediatric and neonatal), as this is used to optimize the calculation of the SpO<sub>2</sub> and pulse numerics.
2. During measurement, ensure that the application site:
  - has a pulsatile flow, ideally with a good circulation perfusion.
  - has not changed in its thickness, causing an improper fit of the sensor.

#### Measurement Procedure

1. Switch on the monitor.
2. Attach the sensor to the appropriate site of the patient.

#### Before Applying the Sensor:

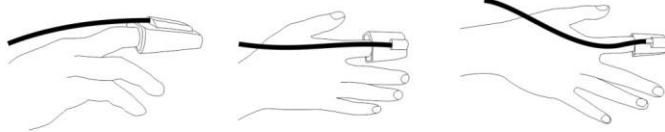
Be sure to understand all warnings listed in the previous section before applying any sensor to a patient. Also, check the sensor as follows:

- ♦ Check the sensor outside and inside. To inspect the inside, gently open the sensor cavity and check splits on or next to the transparent silicone that covers the optical elements.
- ♦ Any sensor showing signs of damage or alteration must not be used for further patient monitoring; instead, dispose of it using proper disposal procedures.

#### Applying Finger/Soft-tip Sensors:

- ♦ Nip the clamp, and choose a site that is well perfused and restricts a conscious patient's movements least. The right finger of the non-dominant hand is preferred. Alternatively, the other digits on the non-dominant hand may be used.

- ◆ The grate toe or long toe (next to the grate toe) may be used on restrained patients or patients whose hands are unavailable.
- ◆ Place the finger into the sensor according to the direction of the symbol on the sensor. The fleshiest part of digit should be covering the detector window.
- ◆ Orient the sensor so that the cable will be running towards the top of the patient's hand.
- ◆ Connect the sensor with the monitor (or with the extension cable if needed).



#### Applying Neonatal Finger (or Toe) Wrap Sensors:

- ◆ When you perform the measurement, position the sensor over the hand or foot with optical components opposite each other.
- ◆ Hold the sensor, and insert stretched strap into slot, hold it there while threading end through latch. If strap is too long, thread it through second latch.
- ◆ Connect the sensor with the monitor (or with the extension cable if needed).



#### Applying Adult/Pediatric Ear Clip Sensor:

- ◆ When you perform the measurement, clip the plastic fixing mechanism on top of the ear; make the ear afford the sensor's weight to avoid the sensor getting loose.
- ◆ Clip the probe onto fleshy part of the lobe with optical components opposite to each other.
- ◆ Connect the sensor with the monitor (or with the extension cable if needed).



3. Plug the connector of the sensor extension cable into the SpO<sub>2</sub> socket.

#### **WARNING**

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours. For neonate, change the measuring site every 20 minutes.

**NOTE:**

- 1 Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.
- 2 Inspect the sensor to ensure that the light emitter and receiver are aligned with each other and there is no gap between the sensor and the finger. All the light emitted by the light emitter must pass through the patient's tissue. The sensor cable should be placed on the back of the hand.
- 3 Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

## 11.4 Measurement Limitations

Certain patient conditions can affect the measurements or cause the loss of the pulse signal.

Inaccurate measurements can be caused but not limited by:

- incorrect sensor application
- high levels of ambient light sources, such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight
- failure to cover the sensor with opaque material in high levels of ambient light conditions
- dysfunctional hemoglobins
- low peripheral perfusion
- excessive or violent patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- externally applied coloring agents (nail polish, dye, pigmented cream)
- defibrillation
- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- electromagnetic interference

Loss of pulse signal can occur for the following reasons:

- the sensor is applied too tightly
- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- there is arterial occlusion proximal to the sensor
- low peripheral perfusion

**NOTE:**

- 1 To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.
- 2 Adjacent SpO<sub>2</sub> sensors may interfere with each other (eg, multiple SpO<sub>2</sub> measurements in the same patient). Be sure to cover the sensor with opaque material to reduce cross-interference.
- 3 Move the sensor to a less active site, and keep the patient still, if possible.
- 4 For Nellcor SpO<sub>2</sub> module, the algorithm automatically extends the amount of data required for measuring SpO<sub>2</sub> and PR depending on the measurement conditions. During normal measurement conditions the averaging time is 6 to 7 seconds. During conditions such as those caused by low perfusion, interference (e.g., external interference such as ambient light or patient movement), or a combination of these, the algorithm automatically extends the amount of data required beyond 7 seconds. If the resulting dynamic averaging time exceeds 20 seconds, the screen will display prompt message "SpO<sub>2</sub> Search Pulse" and SpO<sub>2</sub> and PR will continue to be updated every second. As these conditions extend, the amount of data required continues to increase. If the dynamic averaging time reaches 40 seconds, the screen will display high-level alarm message "SpO<sub>2</sub> No Pulse" indicating a loss-of-pulse condition.

## 11.5 Assessing the Validity of a SpO<sub>2</sub> Reading

You can check the quality of the pleth wave and the stability of the SpO<sub>2</sub> values to assess whether the sensor functions properly and whether the SpO<sub>2</sub> readings are valid. Always use these two indications simultaneously to assess the validity of a SpO<sub>2</sub> reading.

Generally, the quality of the SpO<sub>2</sub> pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO<sub>2</sub> values also reflects the signal quality. Different from varying SpO<sub>2</sub> readings caused by physiological factors, unstable SpO<sub>2</sub> readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO<sub>2</sub> readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

**NOTE:**

- 1 The SpO<sub>2</sub> accuracy has been validated in controlled human studies against arterial blood sample reference measured with a CO-oximeter. SpO<sub>2</sub> measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies are composed of healthy men and women from age 19 to 37 (for **ELITECH** SpO<sub>2</sub> module), from 18 to 50 (for Nellcor SpO<sub>2</sub> module), with various skin pigmentations. Note that the study population was healthy adults and not in the actual intended use population.
- 2 The pulse rate accuracy is obtained by comparison to the pulse rate generated with

an arterial oxygen simulator (also an electronic pulse simulator).

- 3 During monitoring, if the monitor's reading differs significantly from the patient's physiological condition, it indicates that the signal may be disturbed, resulting in an inaccurate reading. In this case, the artifact can disguise as a similar reading, causing the monitor to fail to send an alarm. In order to ensure reliable monitoring, it is necessary to regularly check whether the sensor is wearing properly and the signal quality is good.

## 11.6 SpO<sub>2</sub> Alarm Delay

There is a delay between a physiological event at the measurement site and the corresponding alarm at the monitor. This delay has two components:

1. The time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing time and the sensitivity. The lower the sensitivity configured, the longer the time needed until the numerical values reflect the physiological event.
2. The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the monitor. This delay is the combination of the configured alarm delay time plus the general system delay time.

## 11.7 Perfusion Index (PI)\*

\* Only applicable to the ELITECH SpO<sub>2</sub> module

PI is a numeric value indicating perfusion level. It reflects the perfusion level at the monitoring site.

As the measurement of SpO<sub>2</sub> is based on the pulsation caused by the blood flow through the vessel, PI is in relation to the strength of the pulse. Also, you can use PI as a signal quality indicator for the measurement of SpO<sub>2</sub>.

PI is indicated by a value ranging from 0 to 10. The bigger the value is, the better the perfusion and the signal quality will be. The perfusion level and the signal quality are at their maximum when the value reaches 10. When PI is below 2, it indicates the low perfusion and the poor signal quality at the monitoring site; you need to reposition the sensor or find a better site.

The PI value will be displayed in the SpO<sub>2</sub> parameter area.

## 11.8 Measuring SpO<sub>2</sub> and NIBP Simultaneously

While measuring SpO<sub>2</sub> and NIBP on the same limb simultaneously, the user can set **NIBP Simul** to **On** in **SpO<sub>2</sub> Setup** menu to lock the SpO<sub>2</sub> alarm status until the NIBP measurement ends. If **NIBP Simul** is set to **Off**, low perfusion caused by NIBP measurement may lead to inaccurate SpO<sub>2</sub> readings and therefore cause false physiological alarms.

## 11.9 Setting Pitch Tone

If tone modulation is on, the PR sound lowers when the SpO<sub>2</sub> level drops. In the **SpO<sub>2</sub> Setup** menu, select pitch tone to switch between **On** and **Off**.

## 11.10 Setting Sensitivity

The different sensitivity indicates different refresh frequency. **High** indicates the refresh frequency of SpO<sub>2</sub> value is the most frequent. To change the sensitivity, please follow the steps:

- 1 Select the **SpO<sub>2</sub> Setup** menu;
- 2 Select **Sensitivity** on the interface and select the desired sensitivity from the popup list.

## 11.11 SatSeconds Alarm Management\*

\* Only applicable to the Nellcor SpO<sub>2</sub> module.

\* Not applicable to MFM-CMS.

### 11.11.1 Describing SatSeconds

With traditional alarm management, upper and lower alarm limits are set for monitoring oxygen saturation. During monitoring, as soon as an alarm limit is violated by as little as one percentage point, an alarm is immediately triggered. When the SpO<sub>2</sub> level fluctuates near an alarm limit, the alarm is triggered each time the limit is violated. Such frequent alarms can be distracting.

With the SatSeconds technique, upper and lower SpO<sub>2</sub> alarm limits are set in the same way as traditional alarm management. However, you can also set a SatSeconds limit that allows monitoring of SpO<sub>2</sub> below the selected lower alarm limit and above the selected upper alarm limit for a period of time before an alarm is triggered.

The method of calculation is as follows:

The number of percentage points that the SpO<sub>2</sub> falls outside the alarm limit is multiplied by the number of seconds that the SpO<sub>2</sub> level remains outside that limit. This can be stated as an equation:

$$\text{Points} \times \text{Seconds} = \text{SatSeconds}$$

Where:

Points = SpO<sub>2</sub> percentage points outside of the limit

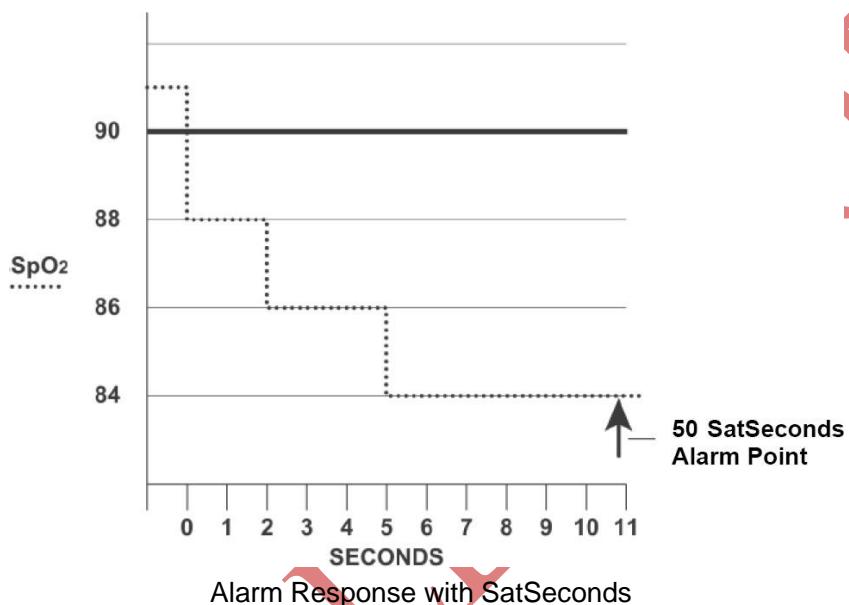
Seconds = number of seconds that SpO<sub>2</sub> remains at that point outside of the limit

The alarm response time, assuming a SatSeconds limit set at 50 and a lower alarm limit set at 90, is described and illustrated below.

In this example, the SpO<sub>2</sub> level drops to 88 (2 points below the limit) and remains there for a period of 2 seconds (2 points × 2 seconds = 4 SatSeconds). The SpO<sub>2</sub> then drops to 86 for 3 seconds and then to 84 for 6 seconds. The resulting SatSeconds values are shown below:

SpO <sub>2</sub>		Seconds	=	SatSeconds
2	×	2	=	4
4	×	3	=	12
6	×	6	=	36
Total SatSeconds			=	52

After approximately 10.7 seconds, a SatSeconds alarm will be triggered, because the limit of 50 SatSeconds has been exceeded. See arrow (↑) in the following figure.



Saturation levels may fluctuate rather than remaining steady for a period of several seconds. Often, the patient SpO<sub>2</sub> may fluctuate above and below the alarm limit, re-entering the non-alarm range several times. During such fluctuation, the monitor integrates the number of SpO<sub>2</sub> points, both positive and negative, until either the SatSeconds limit is reached, or the patient SpO<sub>2</sub> returns within a normal range and remains there.

### 11.11.2 SatSeconds “Safety Net”

The SatSeconds “Safety Net” is for patients whose saturation makes frequent excursions below or above the SpO<sub>2</sub> limit but does not remain in violation long enough for the SatSeconds limit to be reached. If three or more SpO<sub>2</sub> alarm limit violations occur within a 60-second period, an alarm will be triggered even if the SatSeconds limit has not been reached.

### 11.11.3 Setting SatSeconds Duration

You can set SatSeconds to Off or to the duration among **10, 25, 50** and **100**. To configure the SatSeconds settings, enter the **SpO<sub>2</sub> Setup** menu and select the desired SatSeconds setting from the **SatSeconds** list.

# Chapter 12 Monitoring PR

## 12.1 Overview

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart in beats per minute (bpm). You can obtain a pulse from any measured SpO<sub>2</sub> signal or any arterial pressure.

## 12.2 Setting PR Source

The monitor provides PR source options. You can select SpO<sub>2</sub> or arterial pressure labels as the PR source in the **PR Source** list on the **PR Setup** menu.

**NOTE:**

In the **PR Source** list, an arterial pressure label accompanied with a label with brackets indicates this label is in conflict. Do not select a conflicting label as the PR source.

## 12.3 Setting PR Volume

Select **PR Setup > PR Volume**, then select the appropriate setting for the PR volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the PR volume will be off. Beat frequency of pulse has positive correlation with measurement value.

## 12.4 Selecting the Active Alarm Source

In most cases, the HR and PR numerics are identical. In order to avoid simultaneous alarms on HR and PR, the monitor uses either ECG or PR as its active alarm source. To change the alarm source, select either **ECG Setup > Alarm Source** or **PR Setup > Alarm Source**, then select

- **HR:** if you want HR to be the active alarm source.
- **PR:** If you select PR as the active alarm source, the monitor will prompt you to confirm your choice. Be aware that if you select PR as the alarm source, ECG HR alarms are switched off.
- **AUTO:** If the Alarm Source is set to Auto, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and at least one ECG lead can be measured without a technical alarm condition. The monitor will automatically switch to PR for the alarm source if:
  - a valid ECG lead can no longer be measured and
  - a PR source is switched on and available.

The monitor uses the pulse rate from the currently active measurement as system pulse. While PR is the alarm source, all arrhythmia and ECG HR alarms are switched off. If an ECG lead becomes available again, the monitor automatically uses HR as alarm source.

**NOTE:**

Pulse alarms are only generated when the active alarm source is set to **PR**, a pulse source is set as system pulse and pulse alarms are switched on.

# Chapter 13 Monitoring NIBP

## 13.1 Overview

This monitor uses the oscillometric method for measuring NIBP. It can be used for adult, pediatric and neonatal patients. It is also intended for use with pregnant, including pre-eclamptic patients.

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish.

The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ISO 81060-2: 2013) in relation to mean error and standard deviation. In clinical investigation method with a reference sphygmomanometer, the fifth Korotkoff sound was used to determine adult diastolic pressure, and the fourth Korotkoff sound was used to determine pediatric diastolic pressure. The invasive blood pressure is used to determine the neonate pressure in clinical investigation, and the arterial reference sites include umbilical artery, arteria cruralis, axillary artery, brachial artery, dorsalis pedis, and radial artery.

## 13.2 NIBP Safety Information

### **WARNING**

- 1 Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
- 2 Do not measure NIBP on the arm of the same side with a mastectomy.
- 3 Use clinical judgment to decide whether to perform frequent blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
- 4 Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.
- 5 Do not attach the cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, potentially causing harm to patient.
- 6 Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.
- 7 Ensure that the correct patient type is selected before performing measurements. Do not apply the higher adult inflation, overpressure limits and measurement duration for neonatal patients. Not using the neonate mode on a neonatal patient can block the blood flow, potentially causing harm to the patient.
- 8 Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
- 9 Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.

**WARNING**

- 10 NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.
- 11 Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.
- 12 Verifying the calibration is only applicable for adults, and it cannot be operated in automatic measuring interval. Continuous measuring cannot be operated in automatic measuring interval either.

**NOTE:**

- 1 It is suggested that the user should not start NIBP measuring when the low battery displays, or the monitor may be turned off automatically.
- 2 If you spill liquid onto the equipment or accessories, particularly if there is a chance that it can get inside the tubing or the measurement device, contact your service personnel.
- 3 Continuous use of the automatic measuring mode for short intervals may lead to the discomfort of patient. Continuous measuring and automatic measuring in neonatal or pediatric mode may result in tissue damage or ischemia to the patient.
- 4 NIBP measurement can be affected by extremes of temperature, humidity and altitude.
- 5 NIBP measurement value should be explained by qualified professionals.
- 6 The pulse rate based on the NIBP measurement may differ from the heart rate based on the ECG waveform. NIBP measures the number of peripheral pulse pulsations, and the heart rate is measured by the electrical signal of the heart. When the electrical signals of the heart occasionally fail to cause the peripheral blood vessels to pulse or the patient's peripheral perfusion is poor, the difference happens.
- 7 The cumulative use time for the NIBP cuff in a single patient should be less than 30 days.

### 13.3 Measurement Limitations

Measurements are impossible with pulse rate extremes of less than 40 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible in the following situations:

- A regular arterial pressure pulse is hard to detect.
- Patients with cardiac arrhythmias.
- Patients with excessive and continuous movement such as shivering or convulsions.
- Patients with rapid blood pressure changes.
- Patients with severe shock or hypothermia that reduces blood flow to the peripheries.

- Patients with obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery.
- Patients on an edematous extremity.

### 13.4 Measurement Methods

There are four methods of measuring NIBP:

- **Manual** - measurement on demand.
- **Auto** - continually repeated measurements (between 1 and 480 minute adjustable interval). The interval can be user defined, and the default interval of user defined is 2.5 minutes. After the first measurement starts manually, the monitor will automatically measure NIBP as preset interval. When the measurement interval is set to 5 min, 10 min, 15 min, 30 min, 60 min, 90 min, 120 min, 240 min and 480 min, the system will automatically adjust the next measurement time. Here's an example.

Auto Measurement Interval	Current Time	Next Measurement Time
<b>5 min</b>	12:02	12:05, 12:10, 12:15, 12:20, and so forth.
<b>10 min</b>	12:02	12:10, 12:20, 12:30, 12:40, and so forth.
<b>15 min</b>	12:02	12:15, 12:30, 12:45, 13:00, and so forth.
<b>30 min</b>	12:02	12:30, 13:00, 13:30, 14:00, and so forth.
<b>60 min</b>	12:02	13:00, 14:00, 15:00, 16:00, and so forth.
<b>90 min</b>	12:02	13:00, 14:30, 16:00, 17:30, and so forth.
<b>120 min</b>	12:02	13:00, 15:00, 17:00, 19:00, and so forth.
<b>180 min</b>	12:02	13:00, 16:00, 19:00, 22:00, and so forth.
<b>240 min</b>	12:02	13:00, 17:00, 21:00, 1:00, and so forth.
<b>360 min</b>	12:02	13:00, 19:00, 1:00, 7:00, and so forth.
<b>480 min</b>	12:02	13:00, 21:00, 5:00, 13:00, and so forth.

Note: When the completion time of manual measurement to the first hourly time is less than or equal to 30 seconds, the measurement will not be performed at the first hourly time, and the first automatic measurement will be delayed to the next hourly time.

- **Continuous**- the measurement will run consecutively in five minutes, then the monitor enters manual mode.
- **Sequence**- the measurement will preformed at needed phases as preset intervals, after the first measurement starts manually, the monitor will automatically measure NIBP as preset phase and interval. The phase can be selected as **4, 5 and 6**. The interval can be set as **1 min, 2 min, 3 min, 5 min, 10 min, 15 min, 30 min, 60 min, 90 min, 120 min, 180 min, 240 min, 360 min, and 480 min**. The user can also set the measurement times in each phase, there are several selections: **Off, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, Continuous and Off**.

**WARNING**

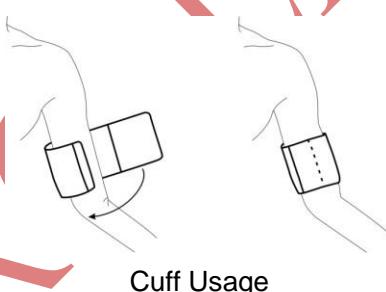
Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purpura, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

## 13.5 Measurement Procedures

To obtain accurate measurements, the following operating steps need to be observed:

1. Ensure the patient position in normal use, including:
  - ◆ Comfortably seated or lie flat, legs uncrossed;
  - ◆ Feet flat on the floor;
  - ◆ Back and arm supported;
  - ◆ middle of the cuff at the level of the right atrium of the heart;
  - ◆ Relax as much as possible, neither talking nor applying external pressure against the cuff. Rest for five minutes in a quiet environment.
2. Connect the air hose to the connector and switch on the monitor.

Apply the blood pressure cuff to the patient's arm or leg and follow the instructions below.



Cuff Usage

- Ensure that the cuff is completely deflated.
- Apply the appropriate size cuff to the patient (About the cuff size selection, please refer to Section *NIBP Accessories*), and make sure that the symbol " $\Phi$ " is over the artery. Ensure the middle of the cuff at the level of the right atrium of the heart that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremity.

Check whether the patient type is appropriately selected. Access the **Patient Setup** menu from **Menu**. Select the required patient **Type** in the **Patient Info**. menu.

3. Select a measurement mode and NIBP Unit (mmHg, kPa or cmH<sub>2</sub>O, 1 mmHg=0.133 kPa, 1 cmH<sub>2</sub>O=1.36 mmHg) in the **NIBP Setup** menu. Refer to Section *Operation Prompts* for details.
4. Press the  button on the front panel or shortcut key  on the shortcut widget

screen to start a measurement.

5. Wait until the first reading is taken.

**NOTE:**

- 1 The width of the cuff is either approximately 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 80%-100% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.
- 2 If an NIBP measurement is suspect, repeat the measurement. If you are still uncertain about the reading, use another method to measure the blood pressure.
- 3 Please make sure the cuff is well connected. A leak of air may cause measurement error.
- 4 Please select the cuff with the suitable size. An unsuitable cuff may cause incorrect measurements.
- 5 Avoid incursion of liquid into the cuff. If this happens, please desiccate the cuff completely.

### 13.5.1 Operation Prompts

#### 1. Manual Measurement

Access the **NIBP Setup** menu and set the **Measure Mode** item to **Manual**. Then press the  button on the front panel or shortcut key  on the shortcut widget screen to start a manual measurement.

#### 2. Automatical Measurement

Access the **NIBP Setup** menu and set the **Measure Mode** item to **Auto**, select time interval as need, then press the  button on the front panel or shortcut key  on the shortcut widget screen.

#### 3. Continuous measurement

Access the **NIBP Setup** menu and pick the **Continuous** item to start a continuous measurement. The continuous measurement will last 5 minutes.

#### 4. Sequence measurement

Access the **NIBP Setup** menu and pick the **Sequence** item to start a sequence measurement.

#### 5. Stopping continuous measurement

During continuous measurement, press the  button on the front panel or shortcut key  on the screen at any time to stop measurement.

### 13.5.2 Correcting the Measurement if Limb is not at Heart Level

To correct the measurement if the limb is not at heart level to the displayed value:

Add 0.75 mmHg (0.10 kPa) for each centimeter higher or	Deduct 0.75 mmHg (0.10 kPa) for each centimeter lower or
Add 1.9 mmHg (0.25 kPa) for each inch higher	Deduct 1.9 mmHg (0.25 kPa) for each inch lower

## 13.6 NIBP Multi-Review Window

To set the display of NIBP measurements, select **NIBP Setup > Review**:

- When it is set to **On**, a window for NIBP measurements will be displayed at the waveform area on the main interface, and the size of this window varies depending on the numbers of displayed waveforms.
- When it is set to **Off**, the window is unavailable on the screen.

## 13.7 Resetting NIBP

When the pressure does not work properly and the system fails to give a message for the problem, pick **Reset** in the **User Maintain > NIBP Maintain** menu to activate self-test procedure, and thus restore the system from abnormal performance.

## 13.8 Calibrating NIBP

NIBP is not user-calibrated. Cuff-pressure transducers must be verified and calibrated, if necessary, at least once every two years by a qualified service professional. See the Service Manual for details.

## 13.9 Leakage Test

Leakage test is used to detect the air tightness of the NIBP pump, valve, and trachea. If not, the system will display NIBP leakage. NIBP leak detection should be performed at least once every two years or when you think the measurement is inaccurate.

### **WARNING**

This pneumatic test other than being specified in the ISO 81060-1 standard is to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test the system gives the prompt that the NIBP airway has air leaks, please contact the manufacturer for repair.

### Procedure of Leakage Test

- Connect the cuff securely with the socket for NIBP air hole.
- Wrap the cuff around the cylinder of an appropriate size, don't wrap the cuff around limbs.
- Make sure the patient type has been set to **Adult**.
- Access **User Maintain > NIBP Maintain**.

5. Select **Leakage Test**. Then the prompt **Leak. Test Running** will appear indicating that the system has started performing leak test.

For ELITECH module:

The system will automatically inflate the pneumatic system to about 180 mmHg. After 20 seconds to 40 seconds, if system leakage has detected, the system will automatically open the deflating valve to stop the leak test and indicates **NIBP Leak**. If no system leakage is detected when the pneumatic system is inflated to 180 mmHg, the system will perform a deflation to an approximate value of 40 mmHg and subsequently perform the second phase leak test. After 20 seconds to 40 seconds, the system will automatically open the deflating valve and provide corresponding indication based on the test result.

For SunTech Module:

**NOTE:**

When applying high pressures; take special care to increase the pressure at a rate that will not cause unwanted overpressure errors (300 mmHg).

Manually inflate the pneumatic system to approximately 250 mmHg. Start the timer and wait 60 seconds for the pneumatic system to reach its pressure equilibrium point. After the waiting period, record the pneumatic pressure level (P1) and wait another 60 seconds and record the pneumatic pressure level again (P2). Safety circuitry on the module only allows the pressure in the pneumatic system to remain above 10 mmHg for 180 seconds. When this safety time limit is exceeded, the valves will open releasing the pressure. Subtract P2 from P1 and this is the leak rate per minute.

6. If the alarm information **NIBP Leak** appears, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the pneumatic test. If the failure prompt still appears, please contact the manufacturer for repair.

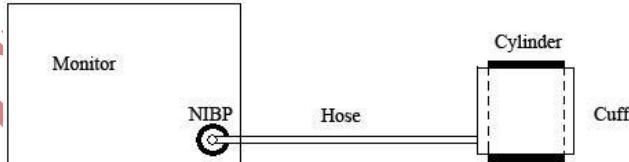


Diagram of NIBP Air Leakage Test

### 13.10 Setting Inflation Mode

To change the inflation mode:

- 1 Select **NIBP Setup > Inflation Mode**;
- 2 Choose **Manual** or **AUTO** from the pull-down list.
  - If **Manual** is chosen, the preset value by users will be adopted as the inflation value when measuring blood pressure.
  - If **AUTO** is chosen, the default value will be adopted as the inflation value when measuring blood pressure.

## 13.11 Cleaning Mode

The cleaning mode can remove the dust and foreign matters in the air valve to ensure the accuracy of NIBP measurement. To start the cleaning mode, please select **User Maintain > NIBP Maintain > Cleaning Mode**, the monitor displays: **Be sure the cuff is disconnected from monitor**, after confirmation and clicking **Start Cleaning** button, cleaning mode starts. The cleaning mode lasts three minutes. In this mode, the monitor displays **Cleaning in progress**, the remaining time of cleaning mode and cuff value are also displayed. When the counting down finishes, the monitor exits cleaning mode automatically, if the user needs to exit the cleaning mode in advance, please click **Stop** button.

When the air pressure is abnormal, the monitor will automatically turn off the cleaning mode and display the prompt message: **Cleaning failed**.

### NOTE:

Cleaning mode is only available when the patient type is adult.

## 13.12 Assisting Venipuncture

The user can use the NIBP cuff to cause a pressure close to diastolic pressure, so as to block the venous blood vessel and therefore help venipuncture. To assist venipuncture:

1. Select **NIBP Setup > Venipuncture**;
2. Select the appropriate **Cuff Pressure** according to the patient type;
3. Select **Start**, the monitor displays: **Venipuncture Starting**.
4. Wait until the monitor prompts **In venipuncture process**. If an abnormal alarm occurs before it, no follow-up operation can be carried out. Restart the procedure after checking if necessary;
5. Puncture vein and draw blood sample;
6. Select **Stop** to deflate the cuff. If you do not deflate the cuff, the cuff automatically deflates when the venipuncture time expires (170 seconds for adult and pediatric patient, 85 seconds for neonatal patient).

During venipuncture, pay attention to the cuff pressure and the countdown displayed in the NIBP numerics area. When the remaining time is 30 seconds, the monitor issues a reminder tone and the countdown displays in red, prompting the user that the venipuncture time is to expire.

### NOTE:

- 1 Only when the monitor exits **Venipuncture** menu, the user can do other operations.
- 2 When the monitor is in DEMO mode, continuous measurement process, manual measurement process, sequence measurement process or auto measurement process, Assisting Venipuncture function is not available.

# Chapter 14 Monitoring TEMP

## 14.1 Overview

Body temperature is measured by means of a thermistor probe (a semiconductor whose resistance changes with temperature) that is applied to the skin or to the rectum.

Two TEMP probes can be used simultaneously to measure two TEMP values, and get the temperature difference. The standard configuration is skin probe for adult.

## 14.2 TEMP Safety Information

### **WARNING**

- 1 Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable of the channel1 from the socket, and then the screen will display the error message **TEMP T1 Sensor Off** and the audible alarm is activated. It is the same to the other channel.
- 2 Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.
- 3 Temperature probes do not need any probe cover; please remember to disinfect the probe after each use on a patient.

### **NOTE:**

- 1 The reference body site temperature is the same as the temperature of the measuring site.
- 2 The cumulative use time for the oral or rectal temperature probe in a single patient should be less than 24 hours.

## 14.3 Selecting TEMP Sensor Type

The user can choose the TEMP sensor type as the temperature signal source.

To configure the TEMP sensor type, select **Menu > Maintenance > User Maintain > Other Setups**, and set **TEMP Sensor** to **YSI-10K** or **YSI-2.252K**.

## 14.4 Switching T1/T2 On/Off

In **Menu > System Setup > Module Switch**, T1 or T2 can be switched on/off separately and won't be affected by each other.

## 14.5 TEMP Monitoring Setup

- With a reusable TEMP probe you can plug the probe directly into the TEMP connector.
- Apply the TEMP probes securely to the patient.
- Switch on the monitor.

It takes 5 minutes for the temperature measurement to stabilize.

## 14.6 Selecting a Temperature for Monitoring

Select the temperature label according to the measurement site. The label is a unique identifier for each type of temperature.

To select the label,

1. Click the TEMP parameter area to enter **TEMP Setup** menu.
2. Select the appropriate label from the list for **T1** and **T2**.

Label	Description
<b>Tskin</b>	Skin temperature
<b>Trect</b>	Rectal temperature
<b>Tcore</b>	Core temperature

### NOTE

Tcore is only available when **TEMP Sensor** is **YSI-2.252K**.

## 14.7 Calculating Temp Difference

The monitor can calculate and display the difference between two temperature values by subtracting the second value from the first. The difference is labeled TD.

# Chapter 15 Monitoring IBP

## 15.1 Overview

IBP is measured by means of a catheter inserted directly into the circulatory system. A pressure transducer connected to the catheter converts the mechanical force exerted by the blood into an electrical signal, which is displayed graphically as pressure versus time on a monitor screen or numerically on digital display.

The monitor measures direct blood pressure of one selected blood vessel through a maximum of two channels, and displays waveforms and pressure of measured direct blood pressure (SYS, DIA and MAP).

## 15.2 IBP Safety Information

### **WARNING**

- 1 The operator should avoid contact with the conductive parts of the appurtenance when it is connected or applied.
- 2 When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.
- 3 Disposable IBP transducer or domes should not be reused.
- 4 If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or enters the transducer or the monitor, contact the Hospital Service Center immediately.
- 5 All invasive procedures have risks to the patient. Use aseptic technique and follow catheter manufacturer's instructions.
- 6 Mechanical shock to the invasive blood pressure transducer may cause severe shifts in zero and calibration, and then cause erroneous readings.
- 7 The longest duration of IBP arterial catheterization is 7 days.

### **NOTE:**

- 1 Use only the pressure transducer listed in the IBP Accessories.
- 2 If measuring intracranial pressure (ICP) on a sitting patient, adjust the transducer on the same level with the top of the patient's ear. Incorrect leveling may lead incorrect values.
- 3 Confirm you set correct alarm limit for labels, the alarm limit you set are stored for its label only. Changing label may change the alarm limit.
- 4 Don't perform IBP calibration when a patient is being monitored.
- 5 When using high frequency ventilation, make sure that the ventilator catheter is not connected to or indirectly connected to the arterial catheter at zero pressure. This can lead to less pressure variations, thus interfere the zeroing process.

## 15.3 Monitoring Procedures

Preparatory steps for IBP measurement:

1. Plug the pressure cable into the IBP socket and switch on the monitor.
2. Prepare the flush solution.
3. Flush through the system, exhaust all air from the tube, and ensure that the transducer and stopcocks are free of air bubbles.
4. Connect the patient catheter to the pressure line, making sure that there is no air present in the catheter or pressure line.
5. Position the transducer so that it is at the same level with the patient's heart, approximately mid-axillary line.
6. For the label name selection, please refer to *Selecting a Pressure for Monitoring*.
7. To zero the transducer, please refer to *Zeroing the Pressure Transducer*.

### **WARNING**

If there are air bubbles in the tube system, you should flush the system with the solution again. The bubbles may cause erroneous pressure readings.

### 15.3.1 Selecting a Pressure for Monitoring

Tell the monitor which pressure you want to monitor by selecting its pressure label. The label is a unique identifier for each type of pressure. When you choose a label, the monitor uses that label's stored settings, for example color, wave scale and alarm settings. The label also determines which algorithm is used to process the pressure signal, so an incorrect label can lead to incorrect pressure values. To select the label, please refer to the following table:

Label	Description
ART	Arterial blood pressure
PA	Pulmonary artery pressure
CVP	Central venous pressure
ICP	Intracranial pressure
LAP	Left atrial pressure
RAP	Right atrial pressure
P1-P2	Alternative non-specific pressure labels

#### **NOTE:**

The pressure option is only valid when the label is P1/P2 and does not take effect under other labels.

### 15.3.2 Zeroing the Pressure Transducer

To avoid inaccurate pressure readings, the monitor requires a valid zero. Zero the transducer in accordance with your hospital policy (at least once per day). You must perform a zero:

- When you use a new transducer or tubing;
- Every time you reconnect the transducer cable to the monitor;
- If you think the monitor's pressure readings are not correct.

When using a pressure module, the zero information is stored in the module.

The zeroing procedure is listed as below:

1. Turn off the stopcock to the patient.
2. Vent the transducer to atmospheric pressure, to compensate for the static and atmospheric pressure exerted on the transducer.
3. In the setup menu for the pressure, select **Zero Channel: XX** or **Zero All**. (**XX** stands for the IBP label name). After confirmation, the user can zero the pressure of certain channel or pressure of all channels. After zeroing, the interface displays the result **and** last calibration time.
4. When you see the message **Zero Ok**, please close the stopcock to atmospheric pressure, and open the stopcock to the patient.

### 15.3.3 Troubleshooting the Pressure Zeroing (Taking Art for Example)

The status message lists the probable cause of an unsuccessful calibration.

Cause	Corrective Action
Art ZERO FAIL	Make sure that the transducer is not attached to the patient.
Art SENSOR OFF, FAIL	Make sure that transducer is not off, and then proceed zeroing.
IN DEMO, FAIL	Make sure that the monitor is not in DEMO mode. Contact service technician if necessary.
PRESSURE OVER RANGE, FAIL	Make sure that the stopcock is vented to atmosphere. If the problem persists, please contact service technician.
PULSATILE PRESSURE ZERO FAIL	Make sure that the transducer is vented to air, not connected to a patient, and try again.

### 15.3.4 IBP Calibration

IBP is not user-calibrated. Calibration should be performed by a qualified service professional as frequently as dictated by your Hospital Procedures Policy.

## 15.4 Changing the IBP Waveform Ruler

The top, middle and bottom rulers are available for each channel of IBP waveform. Users can

adjust the top, middle or bottom rulers manually:

1. Open the menu **Wave Setup** of IBP by clicking on the IBP waveform area.
2. Select a suitable ruler from the options **TopRuler**, **MidRuler** and **BotRuler**.

## 15.5 IBP Waveform Overlapping

The monitor can display IBP overlapped waveforms. To set IBP waveform overlapping:

1. Select **Menu > Maintenance > User Maintain > Other Setups**, and set **IBP Wave Overlapping** to **On** or **Off**.
2. Click the IBP waveform area to show the **IBP Wave Setup** menu.
3. Select **Add IBP Waves** and then select the IBP waves for overlapping from the pop-up list. A maximum of four overlapping waveforms can be displayed.
4. After exiting the interface, the main screen will display the overlapped IBP waves. The flashing label is the main label of the waveform area.

Click the IBP overlapping waveform area on the main screen, and then select **Setup Rulers**. The user can select a suitable ruler for the overlapped waveforms from the options **TopRuler** and **BotRuler**.

## 15.6 Measuring PAWP

PAWP, Pulmonary Artery Wedge Pressure, used to assess the cardiac function, is obtained by introducing a balloon-tipped pulmonary artery flotation catheter into the pulmonary artery. When the catheter is in one of the smaller pulmonary arteries, the inflated balloon occludes the artery allowing the monitor to record changes in the intrathoracic pressures that occur throughout the respiration cycle. The user can view the PAWP measurement result via connected CMS.

### 15.6.1 Measurement Procedures

Pulmonary Artery Wedge Pressure (PAWP) values are affected by fluid status, myocardial contractility, valve and pulmonary circulation integrity. The most accurate PAWP values are obtained at the end of the respiration cycle when the intrathoracic pressure is fairly constant. You can use the respiration waveform as a reference when assessing the PAWP waveform, to ensure constant measurement timing relative to the respiratory cycle.

To start the measurement:

1. On the standard screen interface, select the PA parameter window to enter its setup menu. Then, select **Setup > PAWP Activate** to open the PAWP measurement window.
2. Prepare and check the accessories according to your hospital policy.
3. Wedge the flotation catheter into the pulmonary artery. Then inflate the balloon and pay attention to PA waveform changes on the screen.
4. After obtaining a stable PAWP waveform, press **Freeze** to freeze the waveform. In freeze status, you can adjust the PAWP scale to an appropriate position by selecting **Measure** and moving the cursors up and down according to the clinical experience. Select **Confirm** to

store the PAWP, CVP, HR values. To review the frozen waveform, press **s Browse** and move the cursors up and down as desired. If you need to review the stored PAWP, CVP, HR values, select **PAWP Review**.

5. Deflate the balloon when the monitor prompts you “**Please deflate the balloon!**”.
6. If you need to start a new measurement, select **Remeasure**.
7. Click on **Exit** or select **Setup > PAWP Exit** to exit.

#### **WARNING**

- 1 Prolonged inflation can cause pulmonary hemorrhage, infarction or both. Inflate the balloon for the minimum time necessary to get an accurate measurement.
- 2 If the PAWP (mean) is greater than the PAP (systolic), deflate the balloon and report the incident in accordance with hospital policy, because the pulmonary artery could be accidentally ruptured, and the PAWP value derived will not reflect the patient's hemodynamic state, but will merely reflect the pressure in the catheter or balloon.
- 3 The pressure receiver in the catheter records the pressure change that occurs only at the front of the obstruction.
- 4 Due to the short measurement delay, do not use sidestream CO<sub>2</sub> as a direct reference to determine the end point of the breath in the pressure curve.
- 5 If the balloon is not inflated but the pulmonary artery floating catheter enters the wedge position, the pulmonary artery pressure waveform becomes wedge-shaped. Follow the standard steps to take appropriate action to correct this situation.
- 6 PAWP measurement is not applicable to pediatric and neonate patients.

## 15.7 Calculating CPP

CPP is calculated by subtracting MAP and ICP, it means: CPP=MAP-ICP.

### 15.7.1 Measurement Procedures

To start CPP calculation:

1. Click the ICP parameter area to enter into **ICP Options** interface, select **Setup** to enter into **ICP Setup > CPP Source**; CPP source is defaulted as the currently opened artery, it can be selected as **Art, P1** or **P2**. If there is more than one arterial pressure at the same time, the priority level should be: Art > P1 > P2.
2. Take P1 as example: if P1 is selected as CPP Source, when MAP and ICP are both measured, ICP area will display CPP and its value as below picture, unit is same as ICP. Invalid CPP will display “-?”. CPP will be closed if exit ICP parameter.



## 15.8 Calculating PPV

Pulse Pressure Variation (PPV) is calculated from the specific arterial pressure values, which reflects the variation between the maximal pulse pressure and the minimum pulse pressure in 30 seconds. Pulse pressure is affected by left ventricular-stroke volume, arterial resistance and arterial compliance.

### **WARNING**

- 1 The clinical value of the derived PPV information must be determined by a physician. According to recent scientific literature, the PPV information is restricted to sedated patients who receive controlled mechanical ventilation and without arrhythmia. Whether the calculation results in other situations are clinically significant, applicable and reliable must be determined by a physician.
- 2 In below situations, the calculated PPV value may be inaccurate:
  - the respiration rate is lower than 8 rpm
  - the tidal volume during ventilation is lower than 8 ml/kg
  - patients have acute right ventricular functional disorder (pulmonary heart disease)
- 3 PPV measurement has been validated only for adult patients.

PPV is calculated according to the following equation:

$$\text{PPV} = (\text{PPmax} - \text{PPmin}) / (\text{PPmax} + \text{PPmin}) / 2 * 100\%$$

To select an arterial pressure as PPV source:

1. Click the PPV parameter area to enter **PPV Setup** menu.
2. Select **Art**, **P1**, **P2**, or **AUTO** as **PPV Source**.

Only when P1 and P2 are arterial pressure can they be selected as PPV source. When it is set to **AUTO** and if there is more than one arterial pressure at the same time, the priority level should be: Art > P1 > P2.

# Chapter 16 Monitoring CO<sub>2</sub>

## 16.1 Overview

The EFM provides the sideStream method for CO<sub>2</sub> monitoring. Resironics Sidestream CO<sub>2</sub> module is used for sidestream measuring.

The principle of CO<sub>2</sub> measurement is primarily based on the fact that CO<sub>2</sub> molecule can absorb 4.3μm infrared ray. Absorption intensity is proportional to CO<sub>2</sub> concentration of patient sample, the CO<sub>2</sub> concentration will compute according to the detecting CO<sub>2</sub> absorption intensity of patient sample.

Sidestream measurement takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with a CO<sub>2</sub> sensor. You can measure sidestream CO<sub>2</sub> using the monitor's built-in CO<sub>2</sub> measurement. Respiration rate is calculated by measuring the time interval between detected breaths.

## 16.2 CO<sub>2</sub> Safety Information

### **WARNING**

- 1 Do not use the device in the environment with flammable anesthetic gas.
- 2 The device should be used by trained and qualified medical personnel authorized by the manufacturer.
- 3 Nitrous oxide, elevated levels of oxygen, helium, xenon, halogenated hydrocarbons, and barometric pressure can influence the CO<sub>2</sub> measurement.
- 4 The monitor will be damaged if any pipeline from the CO<sub>2</sub> module's air tube /the air inlet /the air outlet is plugged by water or other materials.
- 5 The accuracy of the CO<sub>2</sub> measurement will be affected by the following reasons: the airway was highly obstructed; the leakage of air way connection or quick variation of environment temperature.
- 6 Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
- 7 Do not place the sensor cables or tubing in any manner that may cause entanglement or strangulation.
- 8 When using mechanical ventilation, gas compensation should be well set. Inappropriate setting may cause incorrect measurement result.
- 9 Resironics module is not equipped with automatic air pressure compensation, before you start the CO<sub>2</sub> measurement for the first time, you must set the correct altitude. Incorrect altitude settings can cause incorrect CO<sub>2</sub> readings.
- 10 Leakage in the respiratory system or sampling system may result in a significant low display of the EtCO<sub>2</sub> value. Always keep all components connected firmly and check for leaks according to standard clinical procedures.

**WARNING**

- 11 The EtCO<sub>2</sub> reading is not always closely related to the paCO<sub>2</sub> value, especially in neonatal patients, and patients with pulmonary disease, with pulmonary embolism or inappropriate ventilation.
- 12 Don't measure CO<sub>2</sub> while nebulized medications are being delivered.
- 13 The CO<sub>2</sub> module temporally stops measuring during zeroing.
- 14 Disconnect the water trap from the holder or set Work Mode to Standby when the module is not in use. Setting path: **CO<sub>2</sub> Setup > Work Mode > Standby**.

**NOTE:**

- 1 After the low battery alarm appears, please do not start the CO<sub>2</sub> measurement, or the monitor may turn off for the low capacity of battery.
- 2 For disposal of hospital waste such as accumulated fluids, calibration gases, sampled gases, where not otherwise specified, follow local regulations regarding disposal of hospital waste.
- 3 If the measurement or sensor fails, stop measurement before the qualified service personnel solves the problem.
- 4 The cumulative use time for the sampling line in a single patient should be less than 30 days.

## 16.3 Monitoring Procedures

### 16.3.1 Zeroing the Sensor

1. Connect the sample line to the module correctly, wait until the monitor's warm-up message disappears, keep the inlet of sample line away from CO<sub>2</sub> source.
2. In the **CO<sub>2</sub> Setup** menu, set **Work Mode** to **Measure**.
3. Select **Zero Calibration** in **CO<sub>2</sub> Setup** menu.
4. After the zeroing calibration is completed, the zeroing message disappears, and the CO<sub>2</sub> monitoring can be performed. If the monitor displays **Breath Detected** or **Zero Required**, zeroing has failed. Zero calibration must be performed again.

Note: CO<sub>2</sub> source includes ventilator, patient's and operator's breath.

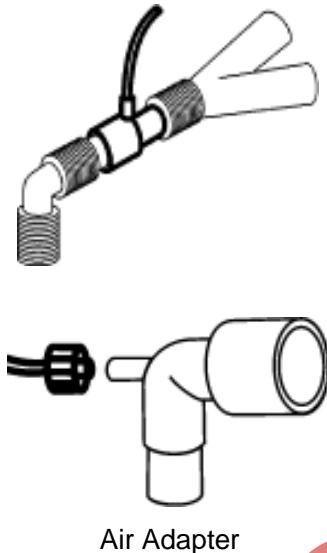
### 16.3.2 Sidestream CO<sub>2</sub> Module

#### 16.3.2.1 Measurement Steps

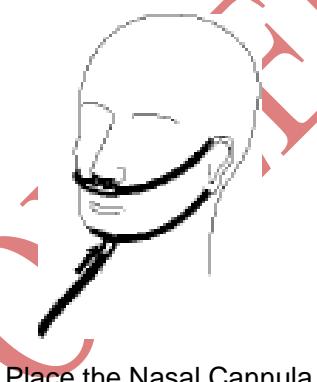
- 1 Plug the sensor cable into the CO<sub>2</sub> input connector on the sidestream CO<sub>2</sub> module. Allow the sensor two minutes for warm-up.
- 2 Connect the cannula, airway adapter, or sample line as required to the sensor. It will click

into place when seated correctly.

- 3 To zero the sensor, please refer to *Zeroing the Sensor*.
- 4 For intubated patients, an airway adapter is required;



For non-intubated patients: Place the nasal cannula onto the patient.



**NOTE:**

- 1 You must perform a zero calibration as described in this procedure each time the ambient temperature changes more than 10 °C (for example during transport).
- 2 Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.
- 3 Disconnect the cannula, airway adapter or sample line from the sensor when they are not in use.
- 4 The sidestream CO<sub>2</sub> module continuously extracts a quantity of gas from the patient's airway per minute. Please do not use this module in any patient who will be affected by this sampling rate.
- 5 If the catheter falls off during the measurement, it is necessary to re-zero after the catheter is well connected, and then measurement can be performed.

### 16.3.2.2 Removing Exhaust Gases from the System

#### **WARNING**

Do not connect the exhaust tube to the ventilator circuit, connect the outlet to a scavenging system, cross infection can occur if sampling gas is returned to the breathingsystem. When using the sidestream CO<sub>2</sub> measurement on patients who are receiving or have recently received anesthetics, please avoid exposing medical staff to anesthetics.

Use an exhaust tube to remove the sample gas to a scavenging system. Attach it to the sidestream sensor at the outlet connector.

## 16.4 Setting CO<sub>2</sub> Corrections

Temperature, water vapor in the patient's breath, barometric pressure, and the proportions of O<sub>2</sub>, N<sub>2</sub>O and Helium in the mixture all influence CO<sub>2</sub> absorption. If values seem inaccurately high or low, check that the monitor is using the appropriate corrections.

There are **Baro Press**, **O<sub>2</sub> Compens**, **Anes Agent** and **Balance Gas** in the **CO<sub>2</sub> Other Setup** menu. The concentration of compensated gas (including O<sub>2</sub> and AG) should be set based on the current gas concentration which is supplied for patient. The selection of balance gas depends on actual situation. For instance, N<sub>2</sub>O should be selected as balance gas if the real balance gas is N<sub>2</sub>O. After settings, the interface will display a dialog box: **Confirm to change the settings?** And the detailed settings are displayed under the warning. Click **Yes** to confirm, and click **No** to cancel the settings.

#### **NOTE:**

Make sure compensation value is correctly set, otherwise the measurement accuracy may be affected.

## 16.5 Setting Apnea Alarm Time

This determines the time limit after which the monitor gives an alarm if the patient stops breathing.

1. Select the **CO<sub>2</sub> Setup > Apnea Alm**;
2. Choose the apnea alarm time from the pop-up list.

#### **WARNING**

Safety and effectiveness of the respiration measurement method in the detection of apnea, particularly the apnea of prematurity and apnea of infancy, has not been established.

## 16.6 Setting CO<sub>2</sub> Waveform

Open the menu **CO<sub>2</sub> Wave Setup** by clicking on the CO<sub>2</sub> waveform area:

- Choose **Mode** and set it to **Curve** or **Filled** from the pop-up list;
- Choose **Sweep** and select a suitable setting from the pop-up list. The bigger the value is, the wider the waveform will be.

## 16.7 Intubation Mode

Intubation mode is suitable for CO<sub>2</sub> monitoring. During general anesthesia, the monitor can be set to intubation mode to eliminate unnecessary alarms. In intubation mode, CO<sub>2</sub> related physiological alarm will be turned off.

To enter intubation mode, follow these steps:

1. Click Intubation Mode in CO<sub>2</sub> Setup;
2. Select Duration in **In Intubation Mode Setup > Duration**, there are two selections: **3 min** and **5 min**.
3. Click Enter Intubation Mode, the monitor will start the intubation mode. During the intubation mode, the monitor will display the intubation mode and countdown in text.

When any of following situation occurs, the monitor will exit the intubation mode:

1. When countdown finishes;
2. Click Exit intubation Mode in CO<sub>2</sub> Setup.

After exiting intubation mode, the monitor will respond the physiological alarm related to CO<sub>2</sub>.

# Chapter 17 Monitoring C.O.\*

\*not available in U.S.A.

## 17.1 Overview

The cardiac output (C.O.) measurement invasively measures cardiac output and otherhemodynamic parameters by using the Thermodilution method. The Thermodilution method is to inject a cold solution into the blood circulation system and measure the temperature changes caused by the cold solution through the thermistor of the pulmonary artery floating catheter, and the C.O. value is calculated by using the temperature dilution curve.

As C.O. is a variable value, a series of measurements must be carried out to obtain a reliable and average C.O. value. Always use the average of multiple measurements for therapy decisions. The monitor can save a maximum of 6 measurement results.

## 17.2 C.O. Safety Information

### **WARNING**

- 1 Make sure that appurtenance applied is in conformity with relevant Medical Device Safety Requirements.
- 2 Appurtenance should be avoided from contact with conductive metal body when being connected or applied.
- 3 All invasive procedures involve risks to the patient. Use aseptic technique and follow catheter manufacturer's instructions.
- 4 The C.O. measurement results may be incorrect during electrosurgery.
- 5 C.O. floating catheter shall be removed or reinserted after 3 days.

### **NOTE:**

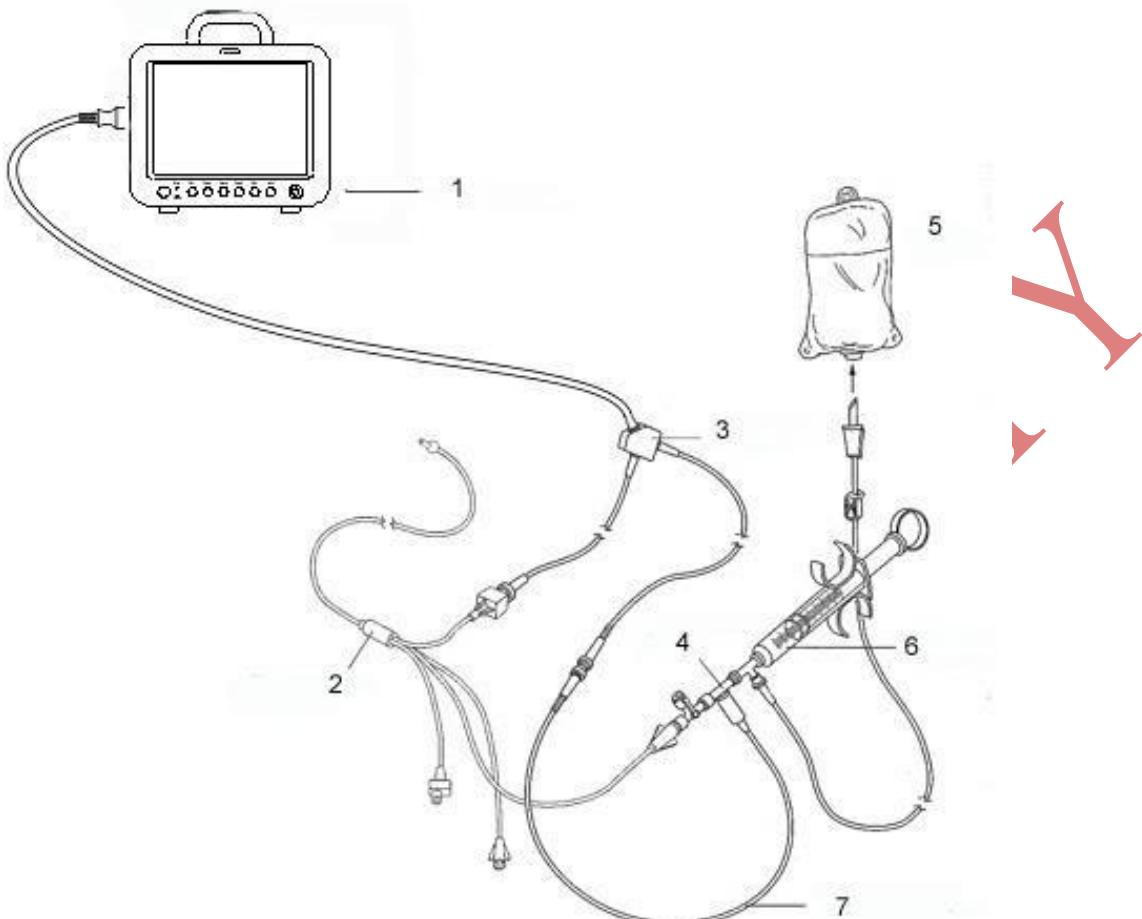
- 1 To replace the catheter thermistor, please enter the catheter computation coefficient into the **Constant** item according to the instruction.
- 2 Please set injection switch well. The calculation of the cardiac output is based on the state of the injection switch at the end of the measurement. Therefore, after the selection of the injection switch is completed, don't change until the measurement is completed.
- 3 Please start C.O. measurement after blood temperature is stable, otherwise the measurement may fail.

## 17.3 C.O. Monitoring

### Preparing Measurement

1. Plug the C.O. cable into the C.O. socket on V-C.O. module and turn on the monitor.

2. Attach the injectate probe connector and catheter thermistor connector to the appropriate parts of the cardiac output interface cable.



1: Monitor; 2: Thermodilution Catheter; 3: Cardiac Output Cable; 4: Injectate Sensor Housing; 5: Injectate; 6: Delivery System; 7: In-line injectate Temperature probe.

#### C.O. Sensor Connection

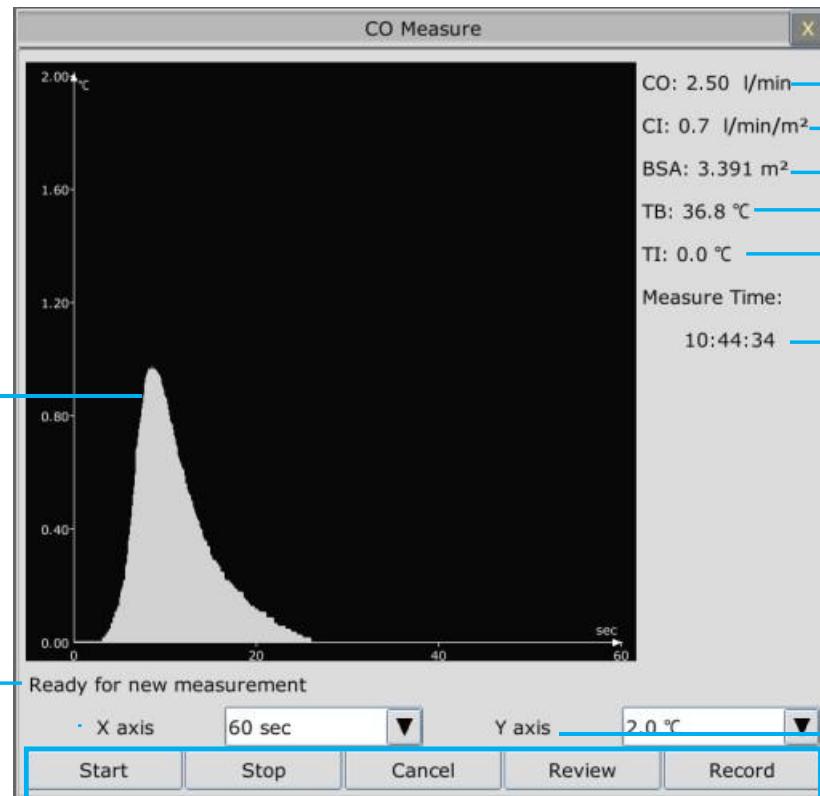
3. Open the patient information window to confirm the patient's height and weight.

4. In C.O. Setup menu, set:

- **C.O. Constant:** The computation constant is associated with catheter and injectate volume. When the catheter is changed, please adjust **Constant** in the **C.O. Setup** menu based on product description provided by the manufacturer. After user's confirmation, the setup takes effect.
- **INJ. TEMP Source:** Select **Auto** or **Manual** from the list, when set as **Manual**, the system directly displays the injectate temperature from INJ. TEMP. Ensure INJ. TEMP is correct, otherwise the C.O. measurement may be affected. When set as **Auto**, the system obtains the injectate temperature through sampling.

### Performing C.O. Measurement

1. Pick the **C.O. Measure** item in the **C.O. Option** menu. The C.O. Measure menu displays as below:



1	Measurement curve	10	<b>X axis:</b> Change the Scale X (time) value. Two modes are available: 0 s to 30 s, 0 s to 60 s. If you start measurement in the 0 s to 30 s mode, it will be switched to 0 s to 60 s mode automatically if the measurement can not finish within 30 seconds. After the switch, no further adjustment can be made to the Scale X.
2	Cardiac Output		
3	Cardiac Index		
4	Body Surface Area		
5	Blood Temperature		
6	Injectate Temperature	11	<b>Y axis:</b> Change the scale Y (temperature) value. Three modes are available: 0 °C to 0.5 °C, 0 °C to 1 °C, and 0 °C to 2.0 °C. Adjust the scale by the temperature differences. A smaller scale results in a larger curve.
7	Start time of the measurement		
8	Prompt message area		
9	Function keys		

The functional keys on the C.O. measure window are explained in the following table:

<b>Start</b>	Start a measurement
<b>Stop</b>	If the blood temperature cannot resume in a considerably long time, the measurement could not stop automatically. Use this button to stop the measurement and display the C.O., CI calculation result.
<b>Cancel</b>	Cancel the processing measurement or cancel the result after measurement.
<b>Record</b>	Print out the curve.
<b>Review</b>	Enter the <b>Review</b> window

2. Measurement should be taken when the message “**Ready for new measurement**” appears on

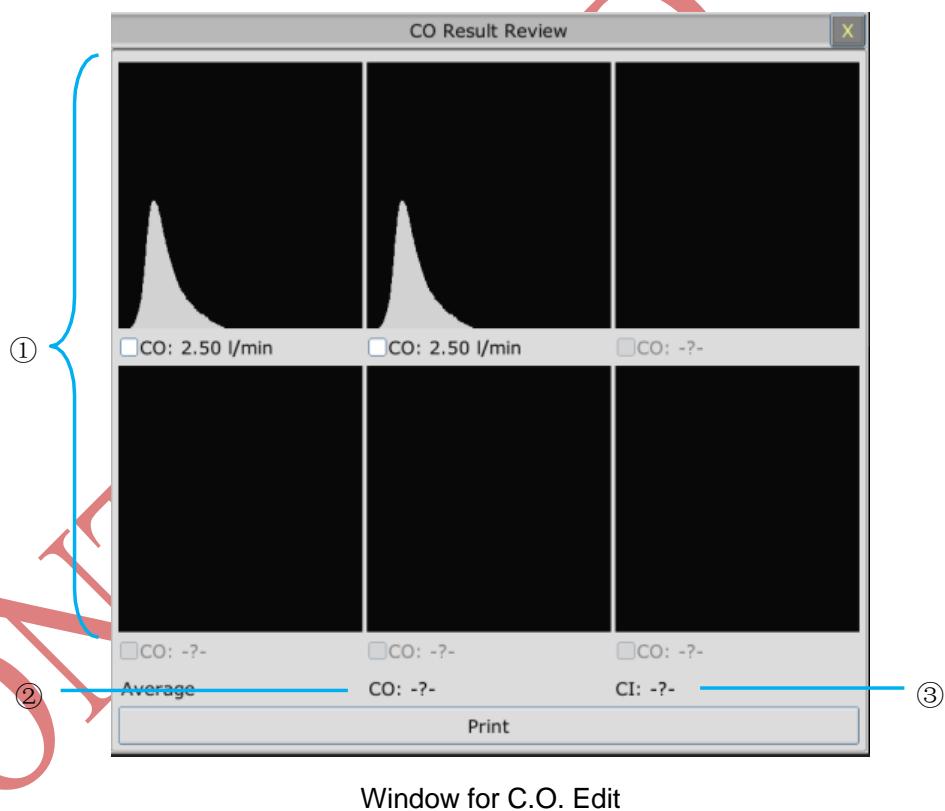
the screen. Press the **Start** button, and then start injection. The thermodilution curve, current blood temperature and the injectate temperature are displayed during the measurement. Curve drawing will stop automatically when the measurement finishes, and the C.O. and CI (2 and 3 in the above figure) will be calculated and displayed on the screen. The monitor will display C.O. in the parameter area and the start measurement time (7 in the above figure).

To ensure the accuracy of the measurement, it is suggested that a reasonable interval should take place between two consecutive measurements. The length of the interval can be set in the C.O. Setup menu (Time unit: second). The interval time counter is displayed on the screen. The next measurement can not be performed until the time reduces to zero and a message **Ready for new measurement** appears. The adjustable range of **Interval** is: 5 to 300 seconds.

Repeat this procedure until you have completed the measurements you want.

A maximum of six measurements can be saved. If you perform additional measurements the earliest measurement will be automatically deleted when a seventh curve is saved.

In C.O. review window, select required curves from the 6 measurement curves, and the monitor will automatically calculate and respectively display the average values of C.O. and CI as following:



Window for C.O. Edit

Contents displayed in the window:

①	Six curves of the six measurements and C.O. value
②	Average value of C.O.
③	Average value of CI

**WARNING**

- 1 Make sure that the computational constant for the measurement is appropriate to the catheter used.
- 2 Before a C.O. measurement is initiated, check the accuracy of patient setup. The calculation of C.O. is related to the patient height, weight, and catheter computation coefficient; therefore, incorrect input will lead to error in calculation.

**NOTE:**

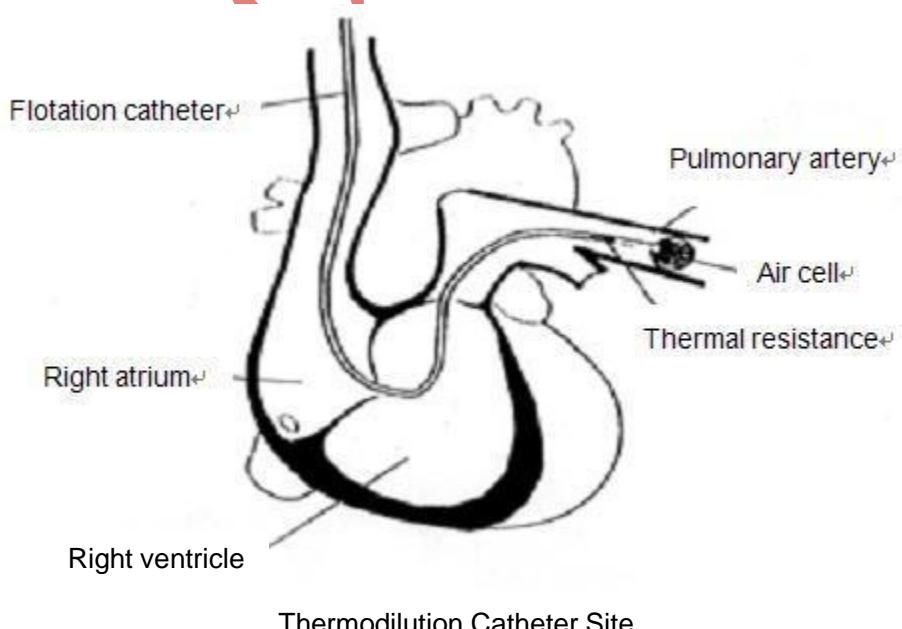
- 1 The blood temperature alarm will not function during C.O. measurement. It will resume automatically when the measurement is over.
- 2 It is strongly recommended that the user must push the injector within four seconds after pressing the **Start** button.
- 3 It is strongly recommended that you wait at least 1 minute (or longer depending on the patient's clinical condition) before starting the next measurement.

## 17.4 Blood Temperature Monitoring

Blood temperature monitoring can function when C.O. measurement is not taken. The blood temperature is measured by the thermistor situated in the distal end of the flotation catheter in the pulmonary artery.

The blood temperature alarm function will not work during the C.O. measurement. When the measurement ends, the function will automatically resume.

The current blood temperature is displayed in the C.O. parameter area.



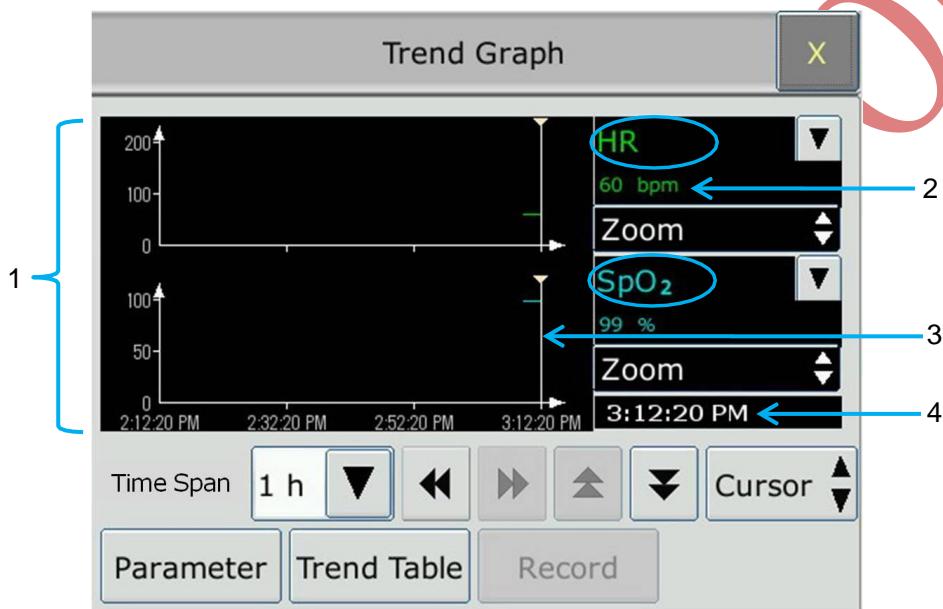
## Chapter 18 Review

The monitor provides 150-hour trend data of all parameters, storage of 1200 NIBP measurement results, 200 alarm events, 200 arrhythmia events, and 50 sets of 12-lead analysis results. This chapter gives detailed instruction for review of all data.

### 18.1 Trend Graph Review

To review the trend graph, please press the **Trend Graph** key  on the shortcut widget screen or select **Menu > Review > Trend Graph**.

In the trend graph, the y-axis stands for the measurement value and x-axis stands for the time. With the exception of NIBP, other trends are displayed as continuous curves.



- 1 Trend curve area
- 2 Trend data: displays measurement values at the cursor indicated time.
- 3 Cursor
- 4 Cursor time

In the trend graph review window:

- Select **Parameter** and you can choose the required parameters to be displayed in the trend graph.
- To display a different parameter's trend, you can either:
  - ◆ Select  beside the parameter name and choose the desired parameter from the pop-up list (as shown in red circle above).
  - ◆ Press the symbols  and  to switch parameters in batch.
- Select **Zoom** to adjust the trend scale. Once the trend scale on the trend graph review interface is adjusted, the trend scale of the corresponding parameter in **TrendScreen** of the main interface will also change.

- Select **Time Span** to change the length of trend data displayed on the current screen. **6 min, 12 min, 30 min, 1 h, 2 h, 4 h, 6 h, 12 h, 24 h, 36 h** and **48 h** are optional.



- Select beside **Cursor** to move the cursor left or right.
- Select and to scroll the screen left and right manually to browse the trend graph.
- Select **Trend Table** to switch to the trend table interface.

## 18.2 Trend Table Review

To review the trend table, please press the **Trend Table** key on the shortcut widget screen or select **Menu > Review > Trend Table**.

In the trend table review window:

- Select **Parameter** and you can choose the required parameters to be displayed in the trend table.
- Select **Interval** to change the interval of the trend data. **1 s, 5 s, 30 s, 1 min, 3 min, 5 min, 10 min, 15 min, 30 min, 60 min** and **NIBP** are optional. Select **NIBP** to view the trend data according to the NIBP measurement time.
- Select , , and to scroll the screen manually to browse the trend table.
- Select **Trend Graph** to switch to the trend graph interface.

### NOTE:

When the interval is selected as **3 min, 5 min, 10 min, 15 min, 30 min** or **60 min**, the newest measurement values are displayed in the right of the trend table.

## 18.3 NIBP Review

To review the NIBP measurement data, please press the **NIBP Review** key on the shortcut widget screen or select **Menu > Review > NIBP Review**.

In the NIBP review window:

- Select **Unit** to change the pressure unit.
- Select and to browse more NIBP measurement data.

## 18.4 Alarm Review

To review the alarm event, please press the **Alarm Review** key on the shortcut widget screen or select **Menu > Review > Alarm Review**.

In the alarm review window:

- Select **Event Type** to choose the required parameter from the popup list and the user can review alarm event of the specific parameters.

- Select **Time Index** to set end time of alarm review.
  - ◆ **Current Time**: the alarm events occurring before the current time are displayed on the alarm event review interface.
  - ◆ **User Define**: the user can define the review time by setting time box displayed on the interface. The alarm events occurring before the **User Define** option are displayed on the alarm event review interface.
- Select  and  to browse more alarm events.

**NOTE:**

The monitor can store a maximum of 200 alarm events. As soon as the alarm event storage is full, the earliest alarm event will be replaced by the latest one.

## 18.5 ARR Review

To review the ARR alarm event, please press the **ARR Review** key  on the shortcut widget screen or select **ECG Setup > ARR Analysis > ARR Review** or **Menu > Review > ARR Review**.

In the ARR review window, the latest arrhythmia events are displayed. Select  and  to browse more ARR alarm events. You may select an alarm event and access the alarm review interface to get more information. On the alarm review interface, you can:

- ◆ Right or left shift the waveform to review the complete 8-second waveform.
- ◆ According to the actual clinical needs, select another name from the pull-down list of **Rename** for the arrhythmia event. Confirm the changes to make the settings take effect.
- ◆ Select **Delete** to remove a specific arrhythmia event.
- ◆ Select **Alarm List** or **Exit** to get back to the arrhythmia review interface.

**NOTE:**

- 1 If there are more than 200 arrhythmia events, the monitor will only keep the recent ones.
- 2 The name of arrhythmia event will be shown on the alarm status area.
- 3 The renaming is only available for the ARR alarm event of the current patient, not for that of the history patient.

## 18.6 12-Lead Analysis Review

To review the 12-lead analysis result, please press the **Analysis Review** key  on the shortcut widget screen or select **Menu > Review > Analysis Review**.

In the 12-lead analysis review window:

- The user can switch between results and waveforms. Select **Waveform** to review the analysis waveforms and **Result** to review the analysis results.

- Select **Delete** to delete the analysis results displayed on the current screen.
- Select  and  to browse more analysis results or waveforms.

## 18.7 ST Segment Review

To review the ST segment, please press the **ECG Setup > ST Analysis > ST Segment Review**.

In the ST segment review window,

- The user can select the lead waveform that want to review.
- The user can select the ST segment to review. There are 20 groups of segments at the most, user can review one ST segment, and can also review all overlapped ST segments.
- The color of ST waveform is consistent with the color of ECG. When only one ST segment is reviewed, this segment is highlighted, the ST value and saved time of the ST Segment is displayed, at the same time, the color of other segments becomes dark.

# Chapter 19 Calculation and Titration Table

The monitor provides calculation function and titration table. Calculations are patient data that are not directly measured but calculated by the monitor.

The monitor can perform drug calculation, hemodynamic calculation, oxygenation calculation, ventilation calculation and renal function calculation.

## NOTE:

- 1 The drug calculation function acts only as a calculator. The patient weights in Drug Dose menu and in Patient Information menu are independent of each other. Therefore changing the Weight in Drug Dose menu will not change the weight in the Patient Information menu.
- 2 The calculation results are for reference only and the calculation significance must be determined by the physician.

## **WARNING**

The correctness of the input parameters and the suitability of the calculated results should be carefully verified. The manufacturer is not liable for any consequences arising from input or operation errors.

## 19.1 Drug Calculation

### 19.1.1 Calculation Procedures

1. The drug calculation window is displayed by selecting **Menu > Common Function > Calculation > Drug Dose**.
2. Select the right pull-down box of the **Drug** option and select the required drug name among the 15 drugs which are listed as follows. And the drug name of **Drug A, Drug B, Drug C, Drug D** and **Drug E** can be defined by the user.
  - Drug A, Drug B, Drug C, Drug D and Drug E
  - Aminophylline
  - Dobutamine
  - Dopamine
  - Epinephrine
  - Heparin
  - Isuprel
  - Lidocaine
  - Nipride
  - Nitroglycerin
  - Pitocin

3. The system generates values that can't be treated the calculation results. The user must enter the correct parameter value based on the doctor's instruction.
4. Manually enter the value of patient weight or directly obtain the value from the monitor by selecting **Get Info**.
5. Enter the correct parameter value.
6. Confirm whether the calculation result is correct.

The following formulas are applied to dose calculation:

Concentrate	= Amount / Volume
INF Rate	= DOSE / Concentrate
Duration	= Amount / Dose
Dose	= Rate × Concentrate
DRIP Rate	= INF Rate / 60 × DROP Size

### 19.1.2 Calculation Unit

Each drug has the fixed unit or unit series to calculate. Among the same unit series, the unit binary varies with the entered parameter value.

The calculation units of the drugs are listed as follows:

Drug	Unit
Drug A, Drug B, Drug C, Aminophylline, Dobutamine, dopamine, Epinephrine, Isuprel, Lidocaine, Nipride, Nitroglycerin	g, mg, mcg
Drug D, Pitocin, Heparin	Ku, mu, Unit
Drug E	mEq

When defining a drug, select Drug A, Drug B, Drug C, Drug D, and Drug E based on the unit series.

#### NOTE:

- 1 The drug calculation is displayed as invalid value before the user edits the drug name and patient weight, and the user can't enter any value.
- 2 Drip Rate and Drop Size are invalid in the neonatal mode.

### 19.1.3 Titration Table

After completing the drug calculation, the user can open the **Titration** on the **Drug Dose** interface.

The user can change the following items in the titration table:

- Basic
- Step
- Dose Type

The data in the titration table will vary with the changes above. And the user can select and to observe more data.

## 19.2 Hemodynamic Calculation

### 19.2.1 Calculation Procedure

1. The hemodynamic calculation interface is displayed by selecting **Menu > Common Function > Calculation > Hemodynamics**.
2. Manually enter the values required on this interface. You can also directly obtain the values of HR, C.O., PA MAP, CVP, and PAWP if they are available from the monitor by selecting **Get Info**.
3. Select **Calculate** to output parameter value.

### 19.2.2 Input Parameters

Items	Unit	English Full Name/Description
PAWP	mmHg	Pulmonary artery wedge pressure
CVP	mmHg	Central venous pressure
C.O.	L/min	Cardiac output
HR	bpm	Heart rate
EDV	ml	End-diastolic volume
AP MAP	mmHg	Mean Artery Pressure
PA MAP	mmHg	Pulmonary artery mean pressure
Height	cm	/
Weight	kg	/
PAP	mmHg	Pulmonary artery pressure

### 19.2.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
CI	L/min/m <sup>2</sup>	Cardiac index	$CI = C.O. / BSA$
BSA	m <sup>2</sup>	Body surface area	$BSA = \text{Weight}^{0.425} \times \text{Height}^{0.725} \times 0.007184$
SV	ml	Stroke volume	$SV = C.O. / HR * 1000$
SVI	ml/m <sup>2</sup>	Stroke volume index	$SVI = SV / BSA$
SVR	DS/cm <sup>5</sup>	Systemic vascular resistance	$SVR = 80 * (AP MAP - CVP) / C.O.$
SVRI	DS·m <sup>-2</sup> /cm <sup>5</sup>	Systemic vascular resistance index	$SVRI = SVR / BSA$

Items	Unit	English Full Name/Description	Formula
PVR	DS/cm <sup>5</sup>	Pulmonary vascular resistance	$PVR = 80 * (PA\ MAP - PAWP) / C.O.$
PVRI	DS·m <sup>2</sup> /cm <sup>5</sup>	Pulmonary vascular resistance index	$PVRI = PVR / BSA$
LCW	kg·m	Left cardiac work	$LCW = 0.0136 * AP\ MAP * C.O.$
LCWI	g·m	Left cardiac work index	$LCWI = LCW / BSA$
RCW	kg·m	Right cardiac work	$RCW = 0.0136 * PA\ MAP * C.O.$
RCWI	kg·m/m <sup>2</sup>	Right cardiac work index	$RCWI = RCW / BSA$
LVSW	g·m	Left ventricular stroke work	$LVSW = 0.0136 * (AP\ MAP - PAWP) * SV$
LVSWI	g·m/m <sup>2</sup>	Left ventricular stroke work index	$LVSWI = LVSW / BSA$
RVSW	g·m	Right ventricular stroke work	$RVSW = 0.0136 * (PAP - PAWP) * SV$
RVSWI	g·m/m <sup>2</sup>	Right ventricular stroke work index	$RVSWI = RVSW / BSA$
EF	%	Ejection fraction	$EF = SV / EDV * 100\%$

## 19.3 Oxygenation Calculation

### 19.3.1 Calculation Procedure

1. Select **Menu > Common Function > Calculation > Oxygenation**.
2. Manually enter the values required on this interface. You can also directly obtain the values of patient height, patient weight, C.O. and FiO<sub>2</sub> if they are available from the monitor by selecting **Get Info**.
3. Select **Calculate** to output parameter value.

### 19.3.2 Input Parameters

Items	Unit	English Full Name/Description
C.I.	L/min/m <sup>2</sup>	Cardiac index
FiO <sub>2</sub>	%	Percentage fraction of inspired oxygen
PaO <sub>2</sub>	mmHg	Partial pressure of oxygen in the arteries
PiO <sub>2</sub>	mmHg	Partial pressure of oxygen in inspired gas
PaCO <sub>2</sub>	mmHg	Partial pressure of carbon dioxide in the arteries
SaO <sub>2</sub>	%	Arterial oxygen saturation
PvO <sub>2</sub>	mmHg	Partial pressure of oxygen in venous blood

Items	Unit	English Full Name/Description
SvO <sub>2</sub>	%	Venous oxygen saturation
Hb	g/L	Hemoglobin
RQ	/	Respiratory quotient
Height	cm	/
Weight	kg	/

### 19.3.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
BSA	m <sup>2</sup>	Body surface area	$BSA = Weight^{0.425} * Height^{0.725} * 0.007184$
VO <sub>2</sub>	ml/(min. m <sup>2</sup> )	Calculated oxygen consumption	$VO_2 = C_{a-v}O_2 * CI$
C a-v O <sub>2</sub>	ml/L	Arterial venous oxygen content difference	$C_{a-v}O_2 = CaO_2 - CvO_2$
O <sub>2</sub> ER	%	Oxygen extraction ratio	$O_2ER = VO_2 / DO_2 * 100\%$
DO <sub>2</sub>	ml/(min. m <sup>2</sup> )	Oxygen transport	$DO_2 = CaO_2 * CI$
PAO <sub>2</sub>	mmHg	Partial pressure of oxygen in the alveoli	$PAO_2 = PiO_2 - PACO_2 \times [FiO_2/100\% + (1-FiO_2/100\%) / RQ]$
AaDO <sub>2</sub>	mmHg	Alveolar-arterial oxygen difference	$AaDO_2 = PAO_2 - PaO_2$
Cc' O <sub>2</sub>	ml/L	Capillary oxygen content	$Cc'O_2 = PAO_2 \times 0.003 + 1.34 \times SaO_2/100\% \times Hb$
Qs/Qt	%	Venous admixture	$Qs/Qt = (Cc'O_2 - CaO_2) / (Cc'O_2 - CvO_2) * 100\%$
C.O.	L/min	Cardiac output	$C.O. = VO_2 / [Ca--v O_2 \times BSA]$
AaDO <sub>2</sub> /PaO <sub>2</sub>	%	AaDO <sub>2</sub> /PaO <sub>2</sub>	$AaDO_2 / PaO_2 = (PAO_2 - PaO_2) / PaO_2 * 100\%$
DO <sub>2</sub> I	ml/(min. m <sup>2</sup> )	Oxygen delivery index	$DO_2I = DO_2 / BSA$
VO <sub>2</sub> I	ml/(min. m <sup>2</sup> )	Oxygen consumption index	$VO_2I = VO_2 / BSA$
CaO <sub>2</sub>	ml/L	Calculated arterial oxygen content	$CaO_2 = (Hb) * 1.34 * SaO_2 / 100\% + (0.0031 * PaO_2)$
CvO <sub>2</sub>	ml/L	Calculated venous oxygen content	$CvO_2 = (Hb) * 1.34 * SvO_2 / 100\% + (0.0031 * PvO_2)$

## 19.4 Ventilation Calculation

### 19.4.1 Calculation Procedure

1. Select **Menu > Common Function > Calculation > Ventilation.**
2. Manually enter the values required on this interface. You can also directly obtain the values of  $\text{FiO}_2$ , RR, PIP and PEEP if they are available from the monitor by selecting **Get Info**.
3. Select **Calculate** to output parameter value.

### 19.4.2 Input Parameters

Items	Unit	English Full Name/Description
$\text{FiO}_2$	%	Percentage fraction of inspired oxygen
RR	rpm	Respiration rate
$\text{PeCO}_2$	mmHg	Partial pressure of mixed expiratory $\text{CO}_2$
$\text{PaCO}_2$	mmHg	Partial pressure of carbon dioxide in the arteries
$\text{PaO}_2$	mmHg	Partial pressure of oxygen in the arteries
VT	ml	Tidal volume
RQ	/	Respiratory quotient
PEEP	cmH <sub>2</sub> O	Positive end-expiratory pressure
PEEPi	cmH <sub>2</sub> O	intrinsic PEEP
$\text{PiO}_2$	mmHg	Inhalation oxygen partial pressure
Ppeak	cmH <sub>2</sub> O	The peak inspiratory pressure

### 19.4.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
$\text{PAO}_2$	mmHg	Partial pressure of oxygen in the alveoli	$\text{PAO}_2 = \text{PiO}_2 - \text{PaCO}_2 \times [\text{FiO}_2/100\% + (1-\text{FiO}_2/100\%) / \text{RQ}]$
$\text{AaDO}_2$	mmHg	Alveolar-arterial oxygen difference	$\text{AaDO}_2 = \text{PAO}_2 - \text{PaO}_2$
$\text{AaDO}_2/\text{PaO}_2$	%	$\text{AaDO}_2/\text{PaO}_2$	$\text{AaDO}_2/\text{PaO}_2 = (\text{PAO}_2 - \text{PaO}_2) / \text{PaO}_2 * 100\%$
MV	L/min	Minute volume	$\text{MV} = \text{VT} * \text{RR} / 1000$
VD	ml	Volume of physiological dead space	$\text{VD} = [(\text{PaCO}_2 - \text{PeCO}_2) * \text{VT}] / \text{PaCO}_2$
VD/VT	%	Physiological dead space in percent of tidal volume	$\text{VD/VT} = (\text{PaCO}_2 - \text{PeCO}_2) / \text{PaCO}_2$
VA	L/min	Alveolar volume	$\text{VA} = (\text{VT} - \text{VD}) * \text{RR} / 1000$

Items	Unit	English Full Name/Description	Formula
Cdyn	ml/cmH <sub>2</sub> O	Compliance dynamic	Cdyn=VT/(Ppeak-PEEP-PEEPi)

## 19.5 Renal Function Calculation

### 19.5.1 Calculation Procedure

1. Select **Menu > Common Function > Calculation > Renal Function.**
2. Manually enter the values required on this interface.
3. Select **Calculate** to output parameter value.

### 19.5.2 Input Parameters

Items	Unit	English Full Name/Description
URK	mmol/L	Urine potassium
URNa	mmol/L	Urinary sodium
Urine	ml/24h	Urine
Posm	mOsm/kgH <sub>2</sub> O	Plasm osmolality
Uosm	mOsm/kgH <sub>2</sub> O	Urine osmolality
SerNa	mmol/L	Serum sodium
SCr	μmol/L	Serum creatinine
UCr	μmol/L	Urine creatinine
BUN	mmol/L	Blood urea nitrogen
UUN	mmol/L	Urine urea nitrogen
Height	cm	/
Weight	kg	/
Type	/	Patient type: Adult, Pediat, Neonat
Gender	/	Male, Female, N/A.

### 19.5.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
URNaEx	mmol/24h	Urine sodium excretion	URNaEx= URNa* Urine/1000
URKEx	mmol/24h	Urine potassium excretion	URKEx= URK* Urine/1000
Na/K	%	Sodium potassium ratio	Na/K =URNa/ URK*100
CNa	ml/24h	Clearance of sodium	CNa= URNa* Urine]/ SerNa

Items	Unit	English Full Name/Description	Formula
CCr	ml/min	Creatinine clearance rate	$CCr = (UCr * Urine) / (SCr * 24 * 60)$
CUUN	ml/min	Urine urea nitrogen clearance rate	$CUUN = UUN * Urine / (BUN * 24 * 60)$
FENa	%	Fractional excretion of sodium	$FENa = (URNa * SCr) / (UCr * SerNa) * 100\%$
FEUr	%	Fractional Excretion of Urea	$FEUr = (SCr * UUN) / (UCr * BUN) * 100\%$
Cosm	ml/min	Osmolar clearance	$Cosm = (Uosm * Urine) / (Posm * 24 * 60)$
CH <sub>2</sub> O	ml/24h	Free water clearance	$CH_2O = (Urine - Uosm) * Urine / Posm$
U/P osm	/	Urine to plasma osmolality ratio	$U/P \text{ osm} = Uosm / Posm$
BUN/SCr	/	Blood urea nitrogen creatinine ratio	$BUN/SCr = (BUN / SCr) * 1000$
U/SCr	/	Urine-serum creatinine ratio	$U/SCr = UCr / SCr$

## Chapter 20 Other Functions

### 20.1 Wi-Fi

Before connecting the monitor to Wi-Fi, you should configure the settings on the monitor following the steps below:

1. Select **Menu > Maintenance > User Maintain**, and input the password.
2. In the **User Maintain** menu, select **Network Maintain**.
3. In the **Network Maintain** menu, select **Wi-Fi** from the **Network Type** list. And click **Config** to open the **Wi-Fi Setup** window. The available networks will be listed in this window.
4. Choose a network from the window, in which the user can check the network's encryption information (**Security**). The user will be prompted to enter the password of that network if a password is required. After entering the password and setting the IPv4 address, the user can click  to connect the network.
5. Or select  to connect the hidden networks. After entering **Network Name**, **Security**, password and setting the IPv4 address, the user can click  to connect the hidden network.

If the monitor is successfully connected to the selected network, it will be indicated by the message **Connected**, and the local IP address of the monitor will be displayed in the **Wi-Fi Setup** window. Also, a symbol indicating the networking state will be displayed on the lower portion of the main screen. The meanings of the networking state symbols are explained below:

-  Wi-Fi signal intensity: Level 4
-  Wi-Fi signal intensity: Level 3
-  Wi-Fi signal intensity: Level 2
-  Wi-Fi signal intensity: Level 1

Click  to review the historically connected networks. After choosing certain network, the user can select **Forget This Network** or **Join This Network**.

If the encryption information of the currently connected network is modified, the network will automatically disconnect and attempt to reconnect. At this time, click  first to ignore this network and then connect manually.

The following symbols may appear when configuring Wi-Fi:

Symbol	Description	Symbol	Description
	Connect to hidden networks		Insecure network (not recommended). Icon color is red.
	View historically connected networks		Hide password

Symbol	Description	Symbol	Description
	Refresh network list		Show password
	Turn the page left and right. to view more networks		Connect the network
	Secure network		Disconnect the network

**NOTE:**

- 1 The obstacle may interfere with data transmission and even cause data loss.
- 2 Known networks will be joined automatically. If no known networks are available, you will have to manually select a network.
- 3 Use the wireless device recommended by the manufacturer, otherwise some exceptional situations such as frequent network disconnection may occur on the monitor.
- 4 The wireless driver is compatible with channels 1-11 only.
- 5 When signal intensity is level 2 or less, signal may be unstable and quality of the signal transmission may be degraded.
- 6 When the monitor is connected to MFM-CMS/Gateway via the wireless network, the user should set the router to a secure encryption/authentication and use the non-dictionary password.
  - ◆ Recommended options: WPA/WPA2 Personal (supports AES/TKIP);
  - ◆ Other options: none or WPA/WPA2 Enterprise (includes TLS/TTLS /PEAP).

## 20.2 Storing Data in the Storage Device

### 20.2.1 Data Stored in the Storage Device

Refer to Section *Data Management* for more information about single patient data volume.

You can choose to **Keep Storing** or **Stop Storing** by selecting **Menu > Common Function > Data Store > if one patient data full**. When the single patient data reach the maximum, the monitor will keep storing or stop storing as selected.

If you choose **Keep Storing**, as soon as the single patient data is full, the earliest data will be replaced by the latest one. When the remaining storage space is less than 15 M, the earliest patient data in the storage space will be deleted in order to store the latest data.

If you choose **Stop Storing**, the monitor will stop data storing and the latest data cannot be stored when the single patient data reach the maximum. For instance, if all the patient data (such as the trend graph, trend table, NIBP measurements, arrhythmia event, alarm event and 12-lead analysis) except waveforms reach the maximum, the monitor will stop storing, while only the waveforms keep storing until they are full. When the remaining storage space is less than 10 M, the monitor

will stop storing new data, prompting insufficient storage space. The default setting of **if one patient data full** is **Stop Storing**.

**NOTE:**

- 1 The storage length varies according to the patient's parameter data volume. When the single patient data storage reaches 240 hours, the monitor will automatically create a new folder for continuous data store. If you chose **Keep Storing**, when the storage space is insufficient, the earliest folder will be deleted and new folder will be created.
- 2 **Threshold Detection** is only applicable to the removable devices.

### 20.2.2 Activating/ Deactivating Data Storing

To activate/ deactivate the data storing function, select **Menu > Maintenance > User Maintain > Other Setups**, and set **Data Store** to **On** or **Off**.

The monitor will stop storing data in the storage device under the following circumstances:

- No storage devices are selected.
- There is no enough space in the storage device for storing data.
- The data storing function is deactivated.
- The removable device is read-only.
- The storage device is damaged.
- The monitor is switched off.
- The power supply is off.

### 20.2.3 Selecting a Storage Device

To configure the storage device, select **Menu > Common Function > Data Store**. The initial default storage device is **Internal Storage**. When the monitor has no internal storage device, the storage device displays **null**.

When user switches the storage device from an internal device to a removable device or switches from one removable device to another removable device, the user password is required.

After you configure the appropriate storage device, click exit. If the storage device is successfully starting data storing, the monitor will be indicated by the symbol . If there is no enough space in storage device, or the storage device is read-only/damaged, the symbol  will be displayed.

---

**CAUTION**

- 1 Not all the removable devices are compatible with the monitor, Use the removable devices recommended by the manufacturer.

**CAUTION**

- 2 Do not set the read-only switch on the removable device to on when the removable device is inserted in the monitor.
- 3 It is recommended to format the USB flash drive to the FAT file type via PC prior to use.

## 20.2.4 Reviewing Data Stored in the Storage Device

To review data stored in the storage device, select **Menu > Review > History Patient**. You can choose to review the storage device as desired from the pop-up list. Choose a patient from the list to review the data including patient information, trend graph, trend table, NIBP measurements, arrhythmia event, alarm event, 12-lead analysis and waveform.

### 20.2.4.1 Reviewing Full Disclosure Waveform

Select **Menu > Review > History Patient > Full Wave** to enter the full disclosure review interface. Select **Wave Setup** to set the desired waveform (Maximum: 1) to be displayed on the full disclosure review interface.

## 20.2.5 Deleting Data Stored in the Storage Device

To delete data of one patient, choose the patient from the list after selecting **Menu > Review > History Patient**, and then click **Delete data** on the **Review** menu. Further confirmation of deletion is required.

To delete data of all patients, select **Menu > Review > History Patient** and click **Delete all data** on the **History Patient Review** menu. Further confirmation is required.

## 20.2.6 Exporting Data Stored in the Internal Storage Device

By USB cable, you can export data stored in the internal storage device.

To export data of one patient from the internal storage, choose the patient from the list after selecting **Menu > Review > History Patient**, and then click **Export Current Data** on the **Review** menu.

To export data of all patients, select **Menu > Review > History Patient** and click **Export all data** on the **History Patient Review** menu.

**NOTE:**

- 1 When the monitor's memory is full, the time to export all the data is about 20 minutes.
- 2 When you export data from the internal storage device, the user password is required, and there is a prompt message in the data transferring interface: **Please input user password first. Attention! Private information included in the data.** If password is correct, the data will be successfully exported into the selected removable device, otherwise, the data export fails, and the interface displays: **Password Error**.

## 20.2.7 Formatting the Internal Storage Device

To format the internal storage device, select **Menu > Maintenance > User Maintain > Other Setups > Format internal storage device**. Further confirmation is required. After Formatting, the monitor displays result including **Format Succeeded** or **Format Failed, Please Retry!**

**NOTE:**

- 1 As soon as the internal storage device is formatted, all the data will be cleared.
- 2 You have no need to restart the monitor after formatting is successful. The internal storage device can be identified and loaded automatically.
- 3 If formatting is failed, try again. Restart the monitor and retry the formatting, or contact the service personnel of the manufacturer if formatting is failed repeatedly.

# Chapter 21 Warning-Score System\*

\*Not available in U.S.A.

User can use warning-score system to get an early warning score based on measurement value or input value of each vital sign. Depending on the score calculated, an action list with appropriate recommendations is displayed. Warning-score system includes MEWS (Modified Early Warning Score) system. Please contact the ELITECH service personnel for activation.

**NOTE:**

- 1 The score results are for reference only and the score significance must be determined by the physician.
- 2 MEWS are applicable to adults only.

## 21.1 Warning-Score Interface

To enter the interface: 1. By shortcut key. Click **Menu > Maintenance > User Maintain > Shortcut Setup** to select **Score**. Then click **Score** shortcut key to enter; 2. By menu. Click **Menu > Common Function > Score** to enter.

To exit the interface: 1. By shortcut key. Click **Score** shortcut key to exit; 2. By menu. Click X button on the top right of the interface.

**NOTE:**

Operations, including power-off, updating or admitting patient, and entering standby or Demo mode, will stop current warning-score function.

## 21.2 Warning-Score Method

Warning-Score method includes score calculator (default) and auto score. If score calculator is selected, user needs to input **HR/PR, TEMP, RR, SYS, SpO<sub>2</sub>, Oxygen, Age and Consciousness** manually, if auto score is selected, user only needs to input **Consciousness** manually, **HR/PR, TEMP, SYS, RR** and other value will be obtained automatically, and then click **Start to Score**. The monitor will calculate and display score result.

**NOTE:**

If any of above information is not completely input, the monitor will prompt information: **Incomplete parameter input, unable to score**.

## 21.3 Warning-Score Criteria

In MEWS interface, select Criteria to check score criteria as following:

Value							
	3	2	1	0	1	2	3
HR (bpm)		$\leq 40$	41~50	51~100	101~110	111~129	$\geq 130$
SYS (mmhg)	$\leq 70$	71~80	81~100	101~199		$\geq 200$	

RESP (rpm)	< 9	9~14	15~20	21~29	$\geq 30$
TEMP (°C)	< 35.0	35.0~38.4		$\geq 38.5$	
Consciousness		A	V	P	U
Note: (1) HR=40, value is 2; (2) SYS=70, value is 3.					

The relationship between consciousness level and its display result is as below:

Consciousness	Displayed Result
Sober	A
Responsive to Voice	V
Responsive to Pain	P
Unresponsive	U

## 21.4 Warning-Score Result

Warning-Score results include parameter value, score value, time and severity level. The relation for value and severity level is as following:

MEWS	Severity Level	Color
0	Non-urgent	Green
$1 \leq \text{MEWS} \leq 3$	Observing	Yellow
$4 \leq \text{MEWS} \leq 6$	Warning	Amber
One single parameter's score value=3 points		
$\text{MEWS} > 7$	Critical	Red

**NOTE:**

The score result can be displayed on the main screen through ticking the **Display on Main Screen** in **Score** Interface.

## 21.5 Warning-Score Trend Table

Trend table provides the monitored patient's scores during a period of time; it includes score time, score parameters and value, score. To check the trend table, click **Trend Table** button in Warning-Score interface. MEWS can support 1200 groups of trend review at least.

**NOTE:**

Trend table is cleared after admitting new patients, entering or exiting Demo mode.

## Chapter 22 Using Battery

This monitor can run on battery power, which ensures its uninterrupted operation even when DC power supply is interrupted. The battery recharges whenever the monitor is connected to the DC power source. During monitoring, if the DC power is interrupted, the monitor will take power from the internal battery. If the monitor is powered by battery, the monitor will switch off automatically before the battery is completely depleted.

### 22.1 Battery Safety Information

#### **WARNING**

- 1 Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.
- 2 The service life of the battery depends on the service frequency and time. The service life of the battery is about three years if the battery is well maintained and stored. The service life of the battery may shorten if it is used inappropriately. If the battery life is exhausted and not replaced in time, it may cause damage or heat to the device.
- 3 Periodic checks on the battery performance are required. Change the batteries if necessary.
- 4 Do not connect the positive (+) and negative (-) terminals with metal objects, and do not put the battery together with metal objects, which can result in short circuits.
- 5 Do not unplug the battery when the monitor is working.
- 6 Do not heat or throw the battery into a fire.
- 7 Do not use, leave the battery close to fire or other places where temperature may be above 60 °C.
- 8 Do not immerse, throw, or wet the battery in water/seawater.
- 9 Do not destroy the battery: do not pierce the battery with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not disassemble or modify the battery.
- 10 The recommended battery can only be used for this monitor. 11  
Do not solder the leading wire and the battery terminal directly.
- 12 If liquid leaking from the battery gets into your eyes, do not rub your eyes. Wash them well with clean water and go to see a doctor immediately. If liquid leaks of the battery splash onto your skin or clothes, wash well with fresh water immediately.
- 13 Keep away from fire immediately when leakage or foul odor is detected.
- 14 Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.
- 15 Do not use a battery with serious scratch or deformation.
- 16 Use the battery with similar performance, which can extend the service life of the battery.

**WARNING**

- 17 When the monitor is running on battery power, do not replace the battery during monitoring patients; or the monitor will be powered off, which may result in patient injury.
- 18 Do not place battery in the monitor with the (+) and (-) in the wrong way.

## 22.2 Battery Power Indicator

The indicator labeled Battery on the front panel of the monitor illuminates in green when the monitor is battery powered and illuminates in yellow when battery is being charged. The indicator is not illuminated when the monitor is not powered or when AC power is applied.

## 22.3 Battery Status on the Battery

Four LED indicators on the battery show the battery power remaining. When you press the button, the LED indicators illuminate.



Remaining battery power: 80% to 100%



Remaining battery power: 60% to 80%



Remaining battery power: 40% to 60%



Remaining battery power: 20% to 40%



Remaining battery power: 10% to 20%



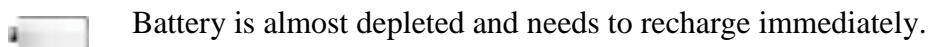
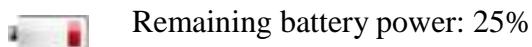
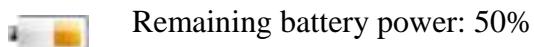
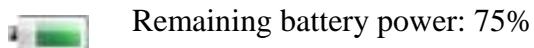
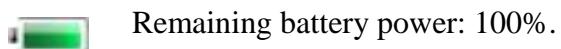
Remaining battery power: 0% to 10%. Battery low alarm-red light flickers.



Battery is running out

## 22.4 Battery Status on the Main Screen

Battery status symbols show the status of the battery and the battery power remaining.



## 22.5 Checking Battery Performance

The performance of rechargeable battery may deteriorate over time. Battery maintenance as recommended here can help to slow down this process.

1. Disconnect the patient from the monitor and stop all monitoring and measurement.
2. Switch the monitor power on and charge the battery for more than 6 hours continuously.
3. Disconnect monitor from mains power and let the monitor run until there is no battery power left and the monitor shuts off.
4. The running time of the battery reflects the battery performance.

If the running time is obviously less than the specified time in the specification, please change the battery or contact the service personnel.

## 22.6 Charging the Battery

A battery can be charged in a monitor during monitoring. In certain situations, internal temperature conditions may mean that the battery will not charge. This is sometimes necessary to protect the battery from damage, and does not indicate a malfunction.

## 22.7 Replacing the Battery

To install or replace the battery, please follow the procedure:

1. To open the battery door, press the battery compartment latch according to the indication on the bottom.
2. Remove the battery from the compartment.
3. Insert a new battery into the battery compartment.
4. Close the battery door.

## 22.8 Recycling the Battery

When the battery no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly.

### **WARNING**

Do not disassemble the battery, put it into fire or cause it to short circuit. It may ignite, explode or leak, causing personal injury.

## 22.9 Maintaining the Battery

To prolong the life of the battery, there is current limitation for using battery. Therefore, the monitor which runs on battery power may not be powered on under following circumstances:

1. The battery is damaged.
2. Battery in the monitor is almost empty.

If above-mentioned circumstances are detected, recharge the battery or use another one battery with similar capacity.

### **CAUTION**

- 1 Batteries should be conditioned regularly to maintain their useful life.
- 2 Remove the batteries from the monitor if they are not used for a longer period of time. And recharge the batteries at a minimum of every 6 months when they are stored.
- 3 Discharge the battery completely once every month.

## Chapter 23 Care and Cleaning

Only use substances approved by the manufacturer and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

The manufacturer has validated the cleaning and disinfection instructions included in this user manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

### 23.1 General Points

Keep your monitor, cables and accessories free of dust and dirt. To prevent the device from damage, please follow the procedure:

- Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute according to the manufacturer's instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the system.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the monitor and reusable accessories after they are cleaned and disinfected.

#### **CAUTION**

If you spill liquid on the equipment, battery, or accessories, or they are accidentally immersed in liquid, contact your service personnel or the manufacturer's service engineer.

### 23.2 Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the monitor and reusable accessories are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

### 23.2.1 Cleaning the Monitor

#### **WARNING**

Before cleaning the monitor, make sure that the monitor is switched off and disconnected from the power line.

To surface-clean the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Wipe the entire exterior surface, including the screen, of the equipment using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain.
3. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
4. Dry the monitor in a ventilated and cool place.

### 23.2.2 Cleaning the Reusable Accessories

#### 23.2.2.1 Cleaning the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
3. Wipe off residual moisture with a dry cloth.
4. Leave the cable assembly to air dry.

#### 23.2.2.2 Cleaning the Blood Pressure Cuff

##### **Cleaning the Cuff:**

1. Take out the air bladder before cleaning.
2. Hand wash the cuff with the cleaning solution; clean the air bladder with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
3. Rinse the cuff and after cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
4. Wipe off residual moisture with a dry cloth.
5. Air dry the cuff thoroughly after cleaning.

##### **Replacing the Air Bladder:**

After cleaning, replace the air bladder into the cuff following the steps below:

1. Roll the bladder lengthwise and insert it into the cuff from the large opening at one end of the cuff.

2. Thread the hose from within the cuff and out through the small hole at the top of the cuff.
3. Adjust the bladder until it is in position.

### 23.2.2.3 Cleaning the SpO<sub>2</sub> Sensor

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution until no visible contaminants remain.
3. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
4. Wipe off residual moisture with a dry cloth.
5. Leave the sensor to air dry.

### 23.2.2.4 Cleaning the IBP Cables/ C.O. Cable

1. Wipe the cables with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
3. Wipe off residual moisture with a dry cloth.
4. Leave the cables to air dry.

### 23.2.2.5 Cleaning the TEMP Sensor

1. Wipe the patient contact area with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
3. Wipe off residual moisture with a dry cloth.
4. Leave the sensor to air dry.

## 23.3 Disinfection

For devices or accessories that have been in contact mucosal surface, High Level disinfection must occur, for all other accessories, low level disinfection is appropriate. Clean the monitor and reusable accessories before they are disinfected. The validated disinfectants for cleaning the monitor and reusable accessories are:

- Ethanol (75%)
- Isopropanol (70%)
- Cidex OPA (High level disinfection of intracavitory temperature probe only)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

**CAUTION**

- 1 Do not use any disinfectant containing additional active ingredients other than those listed, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.
- 2 Although the monitor chemically resistant to most common hospital cleaners, disinfectants and non-caustic detergents, different cleaners or disinfectants are not recommended and may stain the monitor, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.

**WARNING**

The monitor and reusable accessories shall be disinfected to avoid patient cross infection.

### 23.3.1 Disinfecting the Monitor

**WARNING**

Before disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power line.

To disinfect the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Wipe the display screen using a soft, clean cloth dampened with the disinfectant solution.
3. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
4. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
5. Dry the monitor for at least 30 minutes in a ventilated and cool place.

### 23.3.2 Disinfecting the Reusable Accessories

#### 23.3.2.1 Disinfecting the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the cable assembly to air dry for at least 30 minutes.

#### 23.3.2.2 Disinfecting the Blood Pressure Cuff

##### **Disinfecting the Cuff:**

1. Take out the air bladder before disinfection.

2. Wipe the cuff and the air bladder with a soft cloth dampened with the disinfectant solution.
3. Leave the cuff and air bladder to air dry for at least 30 minutes.

#### **Replacing the Air Bladder:**

After disinfection, replace the air bladder into the cuff. Refer to Section *Cleaning the Reusable Accessories* for more information.

#### **NOTE:**

Prolonged use of disinfectant may cause discoloration of the cuff.

#### **23.3.2.3 Disinfecting the SpO<sub>2</sub> Sensor**

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.
3. Wipe off the disinfection solution with a dry cloth after disinfection.
4. Leave the sensor to air dry for at least 30 minutes.

#### **23.3.2.4 Disinfecting the IBP Cable/ C.O. Cable**

1. Wipe the cables with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the cables to air dry for at least 30 minutes.

#### **23.3.2.5 Disinfecting the TEMP Sensor**

The intracavitary TEMP sensors should be reprocessed by high-level disinfection before and after use on each new patient. Cidex OPA is the validated agent for high level disinfection. Refer to the instructions of the disinfectant for the methods of disinfection. High level disinfection has been validated with a 12 minute soak. Rinse and dry according to the labeled instructions of Cidex OPA. Do not dampen the sensor connector.

For the skin TEMP sensors, disinfect them as follows using ethanol or isopropanol only:

1. Wipe the patient contact area with a soft cloth dampened with the disinfectant solution (ethanol or isopropanol).
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the sensor to air dry.

### **23.4 Cleaning and Disinfecting Other Accessories**

For cleaning and disinfecting other accessories, refer to the instructions delivered with the accessories. If the accessories are not accompanied by instructions, refer to this manual for the methods of cleaning and disinfecting the monitor.

# Chapter 24 Maintenance

## **WARNING**

- 1 Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- 2 If you discover a problem with any of the equipment, contact your service personnel, or your authorized supplier.
- 3 The maintenance operations like software upgrade of the device can only be completed by qualified service professionals of the manufacturer.
- 4 Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## 24.1 Inspecting

The overall check of the monitor, including the safety check, should be performed only by qualified personnel every 24 months, and each time after fix up.

The following items should be checked:

- If the environment condition and power supply meet requirement.
- If the power supply cord has damage and insulativity meets requirement.
- If the device and accessories have damage.
- Specified accessories.
- If the alarm system can work properly.
- Battery performance.
- If all monitoring functions are in good conditions.
- If the leakage current meet requirement.

If any damage or abnormality is found, please don't use the monitor and contact local Customer Service Center.

## 24.2 Maintenance Task and Test Schedule

Maintenance shall be carried out at least once every two years, or as specified by local laws. The following tasks are for qualified service professionals of the manufacturer only. Contact a qualified service provider of the manufacturer if your monitor needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

Maintenance and Test Schedule	Frequency
Safety checks. Selected tests on the basis of IEC60601-1	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped.
Check all monitoring functions and measuring functions	At least once every two years, or as needed.

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## Chapter 25 Warranty and Service

### 25.1 Warranty

The manufacturer warrants that the manufacturer's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

- a) damage caused by mishandling during shipping.
- b) subsequent damage caused by improper use or maintenance.
- c) damage caused by alteration or repair by anyone not authorized by the manufacturer.
- d) damage caused by accidents.
- e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, the manufacturer will, at its discretion, repair or replace the defective part(s) free of charge. The manufacturer will not provide a substitute product for use when the defective product is being repaired.

### 25.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

## Chapter 26 Accessories

You can order accessories from the manufacturer's supplies or consult your local representative of the manufacturer for details.

### **WARNING**

- 1 Never reuse disposable transducers, sensors, accessories and their casing that are intended for single use; or only use them on a single patient. Reuse may compromise device functionality and system performance and cause a potential hazard.
- 2 Only use the accessories approved by the manufacturer. Using accessories not approved by the manufacturer may compromise device functionality and system performance and cause a potential hazard. It is not recommended to use accessories supplied by the manufacturer with patient monitors by other manufacturers.
- 3 IBP and C.O. sterilized accessories are already sterilized, refer to the package labeling for detailed method. Do not use a sterilized accessory if its casing is damaged.

### **NOTE:**

Transducers and sensors have a limited shelf life. Refer to the package labeling.

The following cables may not all be available in all countries. Please check availability with your local supplier of the manufacturer.

### 26.1 ECG Accessories

Part Number	Accessories
01.57.471194	3-lead, 12-pin, Defib-proof, Neonate
01.57.471195	3-lead, Snap, IEC, Neonate
01.57.471196	3-lead, Snap, AHA, Neonate
01.57.471197	3-lead, Clip, IEC, Neonate
01.57.471198	3-lead, Clip, AHA, Neonate
01.57.471377	3-lead, 12-pin, Defib-proof, IEC, Clip
01.57.471378	3-lead, 12-pin, Defib-proof, AHA, Clip
01.57.471379	3-lead, 12-pin, Defib-proof, IEC, Snap
01.57.471380	3-lead, 12-pin, Defib-proof, AHA, Snap
01.57.471385	3-lead, 12-pin, ESU-proof, IEC, Clip
01.57.471386	3-lead, 12-pin, ESU-proof, AHA, Clip
01.57.471387	3-lead, 12-pin, ESU-proof, IEC, Snap

Part Number	Accessories
01.57.471388	3-lead, 12-pin, ESU-proof, AHA, Snap
01.57.471481	3-lead, 12-pin, ESU-proof, AHA/IEC, 2.7m, reusable
01.57.471482	3-lead, 12-pin, ESU-proof, AHA/IEC, 5.0m, reusable
01.57.471483	3-lead, 12-pin, Defib-proof, AHA/IEC, 2.7m, reusable
01.57.471484	3-lead, 12-pin, Defib-proof, AHA/IEC, 5.0m, reusable
01.57.471461	3-lead, clip, IEC, 1.0m, reusable
01.57.471462	ECG limb wires, 3-lead, snap, IEC, 1.0m, reusable
01.57.471463	3-lead, clip, AHA, 1.0m, reusable
01.57.471464	ECG limb wires, 3-lead, snap, AHA, 1.0m, reusable
01.57.471226	5-lead, 12-pin, ESU-proof, Adult/pediatric
01.57.471227	ECG trunk cable, 5-lead, 12-pin, ESU-proof, AHA/IEC, 5.0m, reusable
01.57.471228	5-lead, 12-pin, Defib-proof, Adult/pediatric
01.57.471229	5-lead, 12-pin, Defib-proof, Adult/pediatric, Extended
01.13.036620	5-lead, Clip, AHA, Adult/pediatric, Extended
01.13.036621	5-lead, Clip, AHA, Adult/pediatric
01.13.036622	5-lead, Snap, AHA, Adult/pediatric, Extended
01.13.036623	5-lead, Snap, AHA, Adult/pediatric
01.13.036624	5-lead, Clip, IEC, Adult/pediatric, Extended
01.13.036625	5-lead, Clip, IEC, Adult/pediatric
01.13.036626	5-lead, Snap, IEC, Adult/pediatric, Extended
01.13.036627	5-lead, Snap, IEC, Adult/pediatric
01.57.471465	5-lead, 12-pin, Defib-proof, clip, IEC, 3.4m, reusable
01.57.471466	5-lead, 12-pin, Defib-proof, clip, AHA, 3.4m, reusable
01.57.471467	5-lead, 12-pin, Defib-proof, snap, IEC, 3.4m, reusable
01.57.471468	5-lead, 12-pin, Defib-proof, snap, AHA, 3.4m, reusable
01.57.471473	5-lead, 12-pin, ESU-proof, IEC, clip, 3.4m, reusable
01.57.471474	5-Lead, 12-pin, ESU-proof, clip, AHA, 3.4m, reusable
01.57.471475	5-Lead, 12-pin, ESU-proof, snap, IEC, 3.4m, reusable

Part Number	Accessories
01.57.471476	5-lead, 12-pin, ESU-proof, snap, AHA, 3.4m, reusable
01.57.040203	12-lead, Snap, IEC, Adult/pediatric
01.57.109101	12-lead, Snap, AHA, Adult/pediatric
01.57.471072	ECG trunk cable, 10-lead, Defib-proof, AHA, 2.6m, reusable
01.57.471168	ECG trunk cable, 10-lead, Defib-proof, IEC, 2.6m, reusable
01.57.471169	ECG limb wires, 10-lead, clip, AHA, 0.9m, reusable
01.57.471163	ECG limb wires, 10-lead, clip, IEC, 0.9m, reusable
01.57.471276	ECG CONDUCTIVE ADHESIVE ELECTRODES
01.57.471056	ECG Electrodes, adult, disposable, 30 pieces
01.57.471060	ECG Electrodes, adult, disposable, 100 pieces
01.57.471057	ECG Electrodes, child, neo disposable, 50 pieces
01.57.471897	Disposable ECG Electrodes
01.57.471898	Disposable ECG Electrodes
01.57.471858	Disposable ECG Electrodes, 30 PCS/Set
01.57.471859	Disposable ECG Electrodes, 50 PCS/Set
01.57.471862	Disposable ECG Electrodes, 100 PCS/Set
01.57.471861	Disposable ECG Electrodes, 10 PCS/Set

## 26.2 SpO<sub>2</sub> Accessories

Part Number	Accessories
<b>For ELITECH Module</b>	
02.01.210120	SH1 Adult Reusable SpO <sub>2</sub> Sensor (DB9)
02.01.210673	SH3 Neonate Wrap SpO <sub>2</sub> Sensor
02.01.210122	SH4 Adult Silicone Soft-tip SpO <sub>2</sub> Sensor
02.01.210121	SH5 pediatric Silicone Soft-tip SpO <sub>2</sub> Sensor
01.57.471068	7-pin SpO <sub>2</sub> adapter cable
01.57.471235	SHD-A SpO <sub>2</sub> Sensor, adult, disposable
01.57.471236	SHD-P SpO <sub>2</sub> Sensor, pediatric, disposable

Part Number	Accessories
01.57.471237	SHD-I SpO <sub>2</sub> Sensor, Infant, disposable
01.57.471238	SHD-N SpO <sub>2</sub> Sensor, Neonate, disposable
02.57.225000	SpO <sub>2</sub> Sensor, Ear Clip, Adult/Pediatric, 1m, reusable
<b>For Nellcor Module</b>	
01.15.30043	Nellcor Reusable Adult SpO <sub>2</sub> Sensor (DS-100A OxiMax)
01.15.40096	Nellcor Reusable Adult/Neonate SpO <sub>2</sub> Sensor (OXI-A/N OxiMax)
01.57.471069	Nellcor SpO <sub>2</sub> Extension cable (Compatible with Nellcor OXI-Max SpO <sub>2</sub> module and Nellcor sensor)
01.57.040436	Nellcor forehead sensor, Adult/Pediatric, >10 kg, MAX-FAST
01.57.040437	Nellcor strip winding sensor, Pediatric/Infant, 3 kg-40 kg, hand/foot, OXI-P/I
01.57.040438	Nellcor multisite sensor, > 1 kg, hand, D-YS
01.57.040440	Nellcor sticking sensor, Adult, > 30 kg, hand, MAX-A/MAX-AL
01.57.040441	Nellcor sticking sensor, Neonatal/Adult < 3 kg or > 40 kg, foot, MAX-N
01.57.040442	Nellcor sticking sensor, Infant, 3 kg-20 kg, foot, MAX-I
01.57.040445	Nellcor sticking sensor, Pediatric, 10 kg-50 kg, hand, MAX-P

## 26.3 NIBP Accessories

Part Number	Accessories
<b>For ELITECH Module</b>	
01.57.471323	NIBP Cuff, Neonate, 10 cm-15 cm, reusable
01.57.471324	NIBP Cuff, Neonate, 6 cm-11 cm, reusable
01.57.471326	NIBP Cuff, E5, Infant, 10 cm -15 cm, reusable
01.57.471327	NIBP Cuff, E6, Small child, 13 cm -17 cm, reusable
01.57.471328	NIBP Cuff, E7, Child, 16 cm -21.5 cm, reusable
01.57.471329	NIBP Cuff, E8, Small adult, 20.5 cm-28 cm, reusable
01.57.471330	NIBP Cuff, E9, Adult, 27 cm -35 cm, reusable
01.57.471331	NIBP Cuff, E10, Large adult, 34 cm -43 cm, reusable

Part Number	Accessories
01.57.471157	NIBP Cuff, neonatal #1, 3 cm -6 cm, disposable
01.57.471158	NIBP Cuff, neonatal #2, 4 cm -8 cm, disposable
01.57.471159	NIBP Cuff, neonatal #3, 6 cm -11 cm, disposable
01.57.471160	NIBP Cuff, neonatal #4, 7 cm -13 cm, disposable
01.57.471161	NIBP Cuff, neonatal #5, 8 cm -15 cm, disposable
01.59.473007	NIBP Hose
<b>For SunTech Module</b>	
01.57.471157	NIBP Cuff, neonatal #1, 3 cm -6 cm, disposable
01.57.471158	NIBP Cuff, neonatal #2, 4 cm -8 cm, disposable
01.57.471159	NIBP Cuff, neonatal #3, 6 cm -11cm,disposable
01.57.471160	NIBP Cuff, neonatal #4, 7 cm -13cm,disposable
01.57.471161	NIBP Cuff, neonatal #5, 8 cm -15cm,disposable
01.57.471494	APC Cuff, Child (Green), Range: 12 cm– 19 cm
01.57.471495	APC Cuff, Small Adult (Royal Blue), Range: 17 cm – 25 cm
01.57.471496	APC Cuff, Adult (Navy Blue), Range: 23 cm – 33 cm
01.57.471497	APC Cuff, Large Adult (Burgundy), Range: 31 cm – 40 cm
01.57.000974	OPC Cuff, Child, rang: 12 cm -19 cm
01.57.000976	OPC Cuff, Small Adult, rang: 17 cm -25 cm
01.57.000977	OPC Cuff, Adult, rang: 23 cm -33 cm
01.57.000978	OPC Cuff, Large Adult, rang: 31 cm -40 cm

## 26.4 TEMP Accessories

Part Number	Accessories
01.15.040226	Temperature Probe, Skin, adult, 2-Pin (2.252 K/25 °C)
01.15.040227	Temperature Probe, rectal/oral, adult, 2-Pin (2.252 K/25 °C)
01.15.040225	Temperature Probe, Skin, adult, 2-Pin (10 K/25 °C)

Part Number	Accessories
01.15.040228	Temperature Probe, rectal/oral, adult, 2-Pin (10 K/25 °C)
01.15.040253	Temperature Probe, Skin, Neonate/Infant, 2-Pin (2.252 K/25 °C)
01.15.040254	Temperature Probe, rectal/oral, Neonate/Infant, 2-Pin (2.252 K/25 °C)
01.15.040255	Temperature Probe, Skin, Neonate/Infant, 2-Pin (10 K/25 °C)
01.15.040256	Temperature Probe, rectal/oral, Neonate/Infant, 2-Pin (10 K/25 °C)

## 26.5 IBP Accessories

Part Number	Accessories
01.57.471070	Pressure transducer interface cable, BD, use with 01.57.471664
01.57.471172	Pressure transducer interface cable, EDWARD, use with 01.57.471665
01.57.471173	Pressure transducer interface cable, HOSPIRA, use with 01.57.471666
01.57.471166	Pressure transducer interface cable, UTAH
01.57.471836	IBP Pressure transducer interface cable/12pin, B.Braun type interface
01.57.40121	IBP Pressure transducer kit, BD, disposable (BD DT-4812)
02.57.471281	ICP transfer cable
01.57.471664	Disposable Pressure transducer PT161103, compatible with BD
01.57.471665	Disposable Pressure transducer PT151103, compatible with Edward
01.57.471666	Disposable Pressure transducer PT141103, compatible with Abbott
01.57.471880	Reusable pressure transducer
01.57.471881	Disposable dome
01.57.471971	12 pin, dual channel, IBP cable (BD)
01.57.471972	12 pin, dual channel, IBP cable (EDWARD)
01.57.471973	12 pin, dual channel, IBP cable (HOSPIRA)
01.57.471974	12 pin, dual channel, IBP cable (UTAH)
01.57.471975	12 pin, dual channel, IBP cable (B.Braun)

## 26.6 CO<sub>2</sub> Accessories

Part Number	Accessories
01.57.078139	Disposable CO <sub>2</sub> Nasal Cannula - Adult (Respironics 3468ADU-00)
01.57.078151	Adult/Pediatric Airway adapter kit with dehumidification tubing (Respironics 3473ADU-00)
01.57.078154	Disposable Sampling Line Kit with Dehumidification Tubing (Respironics 3475-00)
01.57.078142	Adult Nasal CO <sub>2</sub> with O <sub>2</sub> delivery sampling cannula (Respironics 3469ADU-00)
01.57.078143	Pediatric Nasal CO <sub>2</sub> with O <sub>2</sub> delivery sampling cannula (Respironics 3469PED-00)
01.57.078144	Infant Nasal CO <sub>2</sub> with O <sub>2</sub> delivery sampling cannula (Respironics 3469INF-00)
01.57.101019	Adult Nasal/Oral CO <sub>2</sub> sampling cannula (Respironics 3470ADU-00)
01.57.101020	Pediatric Nasal/Oral CO <sub>2</sub> sampling cannula (Respironics 3470PED-00)
01.57.101021	Adult Nasal/Oral CO <sub>2</sub> with O <sub>2</sub> delivery sampling cannula (Respironics 3471ADU-00)
01.12.031598	Adult/Pediatric Airway adapter kit (Respironics 3472ADU-00)
01.57.078140	Disposable CO <sub>2</sub> Nasal Cannula - Pediatric (Respironics 3468PED-00)
01.57.078141	Disposable CO <sub>2</sub> Nasal Cannula - Infant (Respironics 3468INF-00)
01.57.078152	Pediatric/Infant Airway adapter kit with dehumidification tubing (Respironics 3473INF-00)

## 26.7 C.O. Accessories

Part Number	Accessories
01.57.471071	Cardiac output cable
01.13.40119	In-line Injection temperature probe (BD 684056-SP4042)
01.57.40120	In-line Injection temperature probe housing (BD 680006-SP5045)
01.57.100175	Control Syringe (Medex MX387)
01.57.40121	IDTX Enhanced SPU Transducer/BD DT-4812

**NOTE:**

The Thermodilution Catheter is required when measuring C.O.. Swan-Ganz catheter (Type 131HF7 and 741HF7), manufactured by Edwards Lifesciences Corporation, has been validated to be compatible with the monitor. Refer to Edwards for more details.

## 26.8 Other Accessories

Part Number	Accessories
02.01.211029	DC-DC on-board power adapter assembly
01.13.037040	on-board power adapter power cord
21.21.064213	Rechargeable Intelligent Lithium-Ion Battery (11.1 V, 2400 mAh)
01.54.456165	User manual
21.21.064216	Power Adapter
21.12.032128	Power Plug (EUR Standard)
83.60.260648	EFM module
02.04.243318	Mounting plate for PM PRO-2
02.04.243319	Bedrail Clamp
02.04.243320	PM PRO-2 wall mounting bracket assembly kit (With package)
01.56.466270	Carrying bag for PM PRO-2
01.56.465615	Bedrail Mounting Belt
01.56.465553	Carry Belt

**NOTE:**

The part name may vary depending on context, but the part number is constant.

# A Product Specifications

## NOTE:

The performance of the equipment with  $\star$  mark is determined to be essential performance.

## A.1 Classification

Anti-electroshock type	Class II equipment and internal powered equipment		
Anti-electroshock degree	ECG (RESP), TEMP, IBP, C.O. SpO <sub>2</sub> , NIBP, CO <sub>2</sub>	CF BF	
Ingress Protection	IP44 (protected against splashing water and solid foreign objects $\geq 1.0$ mm diameter)		
Working system	Continuous operation equipment		
Compliant with Standards	IEC 60601-1: 2005+A1 :2012; IEC 60601-1-2: 2014; EN 60601-1: 2006+A1 :2013; EN 60601-1-2: 2015; IEC 60601-2-49: 2011		

## A.2 Physical Specifications

Product	Dimension	Max Weight	Comments
PM PRO-2	185 mm (W) $\times$ 165 mm (H) $\times$ 89 mm (D)	< 1.5 kg	Including battery, without accessories
EFM	207 mm (W) $\times$ 116 mm (H) $\times$ 93.4 mm (D)	< 0.58 kg	Including sidestream CO <sub>2</sub> module.

## A.3 Function Configuration

Product	Standard Configuration	Optional Configuration
PM PRO-2	ECG (3- Electrode, 5- Electrode), RESP, SpO <sub>2</sub> (ELITECH), NIBP (ELITECH), TEMP, Wi-Fi, USB interface	ECG (6- Electrode, 10-Electrode), SpO <sub>2</sub> (Nellcor), NIBP (SunTech), IBP, C.O.
EFM	/	CO <sub>2</sub> (Respironics LoFlo)

Note: There is only one configuration for EFM module.

## A.4 Environmental Specifications

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

<b>Main unit</b>	
Temperature	
Working	+0 °C to +40 °C (32 °F ~ 104 °F)
Transport and Storage	-30 °C to +70 °C (-22 °F ~ 158 °F)
Humidity	
Working	15%RH to 95%RH (non-condensing)
Transport and Storage	15%RH to 95%RH (non-condensing)
Altitude	
Working	680 hPa to 1060 hPa
Transport and Storage	615 hPa to 1060 Pa

<b>EFM</b>	
Temperature	
Working	+0 °C to +35 °C (32 °F ~ 95 °F)
Transport and Storage	-30 °C to +70 °C (-22 °F ~ 158 °F)
Humidity	
Working	15%RH to 95%RH (non-condensing)
Transport and Storage	15%RH to 95%RH (non-condensing)
Altitude	
Working	680 hPa to 1060 hPa
Transport and Storage	615 hPa to 1060 hPa

### NOTE:

The time required for the patient monitor to warm from the minimum storage temperature between uses until it is ready for intended use is at least 2 hours; the time required for the patient monitor to cool from the maximum storage temperature between uses until it is ready for intended use is at least 2 hours.

## A.5 Out-Of-Hospital Transport Requirements

The monitor can be used in transport environments such as a road ambulance. For this purpose, the monitor meets the following requirements:

- EN 1789: 2007+A1: 2010 Road ambulances (Chapter 6 – Medical Devices).
- IEC/EN 60529 IP44 Specification for degrees of protection provided by enclosures.
- Radiated susceptibility 20 V/m according to Complies with ISO 80601-2-61: 2011. (SpO<sub>2</sub>) and ISO 80601-2-55: 2011 (CO<sub>2</sub>).

## A.6 Power Supply

Voltage	DC 10 V – 16 V
Current	1.27 A – 2.3 A

## A.7 Display

Display	Messages
Display screen: 5-inch color TFT, touch screen is configurable Resolution: 800 × 480	One power on/off LED One battery charge LED One DC power LED One physiological alarm LED One technical alarm LED One alarm mute LED

## A.8 Battery

Number	1
Battery Type	Lithium battery
Capacity	11.1 V, 2400 mAh
Operating Time	5.5 hrs (At 25 °C ±2 °C, with (a) new fully charged battery, ECG (RESP)/TEMP/SpO <sub>2</sub> module connected, NIBP automatic measurement mode at interval of 15 minutes, brightness set to “1”.)
Charging Time	14 hrs (The monitor is on or in standby mode, 100% charge) 12.6 hrs (The monitor is on or in standby mode, 90% charge) 2.5 hrs (The monitor is off, 100% charge) 2.3 hrs (The monitor is off, 90% charge)

## A.9 Power Adapter

AC Power Adapter	Input: 100 V - 240 Vac, 40VA; Output: 15 V $\pm$ 5% dc, 24 VA
DC Power Adapter	Input: 12.4 V - 15.1 Vdc or 24.8 V - 30.3 Vdc, 1.6 A max; Output: 15 Vdc, 1 A max

## A.10 Data Management

### Data Review

Trend data	1 hour, resolution: 1 s 150 hours, resolution: 1 min
Alarm events	Up to 200 sets
NIBP measurement data	1200 sets
Arrhythmia events	Up to 200 sets
12-Lead analysis result	Up to 50 sets

Refer to Chapter *Review* for more information about data review.

### Data Storage

A single piece of patient data maximally contains the following information:

Patient information	MRN, name, date of birth, date of admission, gender, type, height, weight, blood type, pace, doctor, bed No., department
Trend graph and trend table	240 hours, resolution: 1 min
NIBP measurement review	1200 sets
Alarm review	200 sets
Arrhythmia event	200 sets
12-lead analysis review	50 sets
Full disclosure waveforms	3-lead/5-lead: 48 hours 12-lead: 35 hours

Refer to Section *Storing Data in the Storage Device* for more information about storing data in the storage medium.

## A.11 ECG

Complies with IEC 60601-2-25: 2011, IEC 60601-2-27: 2011.

Lead Mode	3 Electrodes: I, II, III 5 Electrodes: I, II, III, aVR, aVL, aVF, V 6 Electrodes: I, II, III, aVR, aVL, aVF, and leads responding to Va Vb. 10 Electrodes: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Electrode Standard	AHA, IEC
☆Display Sensitivity (Gain Selection)	1.25 mm/mV ( $\times 0.125$ ), 2.5 mm/mV ( $\times 0.25$ ), 5 mm/mV ( $\times 0.5$ ), 10 mm/mV ( $\times 1$ ), 20 mm/mV ( $\times 2$ ), 40 mm/mV ( $\times 4$ ), AUTO gain
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s
Bandwidth (-3dB)	Diagnosis: 0.05 Hz to 150 Hz Diagnosis 1: 0.05 Hz to 40 Hz Monitor: 0.5 Hz to 40 Hz Surgery: 1 Hz to 20 Hz Enhanced: 2 Hz ~18 Hz Customized: High-pass Filter and Low-pass Filter (Refer to Section <i>Changing the ECG Filter Settings</i> )
☆CMRR (Common Mode Rejection Ratio)	Diagnosis: > 95 dB Monitor: > 105 dB Surgery: > 105 dB Enhanced: > 105 dB Diagnosis 1: > 105 dB (when Notch is turned on) Customized: > 105 dB (Low-pass Filter < 40 Hz) > 95 dB (Low-pass Filter > 40 Hz)
Hum Filter	In diagnosis, Diagnosis 1, monitor, surgery, enhanced modes: 50 Hz/60 Hz (Hum Filter can be turned on or off manually)
☆ Differential Input Impedance	> 5 MΩ
☆Input Signal Range	±10 mV PP
☆Accuracy of Input Signal Reproduction	An error of ±20% of the nominal value of the output or ±100 µV, whichever is greater. The total error and frequency response comply with IEC60601-2-27: 2011, Sect. 201.12.1.101.1.

☆ Electrode Offset Potential Tolerance	$\pm 500 \text{ mV}$
Auxiliary Current (Leads off detection)	Active electrode: $< 100 \text{ nA}$ Reference electrode: $< 900 \text{ nA}$
☆ Recovery Time After Defibrillation	$< 5 \text{ s}$ (measured without electrodes as IEC60601-2-27:2011, Sect. 201.8.5.5.1 requires.)
Leakage current of patient	$< 10 \mu\text{A}$
Scale signal	1 mVPP, accuracy is $\pm 5\%$
☆ System Noise	$< 30 \mu\text{VPP}$
☆ Multichannel Crosstalk	$\leq 5\%$ of the input signal Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.5.
☆ Frequency and Impulse Response	<p>Frequency response: Input a 5 Hz, 1 mV sine wave signal, and the output signal amplitude remains within the range of 71% to 110% at 0.67 Hz and 40 Hz.</p> <p>Input a 1 Hz, 1.5 mV 200 ms triangular wave input signal, and the output shall be within 11.25 mm~15 mm.</p> <p>Impulse response: Displacement value: <math>\leq 0.1 \text{ mV}</math> Slope: <math>\leq 0.3 \text{ mV/s}</math> following the end of the pulse.</p> <p>Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.8.</p>
Sampling frequency	1000 Hz
Sampling channel switch time	$< 80 \mu\text{s}$
A/D precision	24 Bits (Minimum resolution: 0.07533 uV/LSB)
☆ ESU Protection	Cut mode: 300 W Coagulation mode: 100 W Restore time: $\leq 10 \text{ s}$
Electrosurgical Interference Suppression	Test according to ANSI/AAMI EC13:2002, Sect. 5.2.9.14. Complied with ANSI/AAMI EC13:2002, Sect. 4.2.9.14.

Pace Pulse	
Pulse indicator	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met:  Amplitude: $\pm 2$ mV to $\pm 700$ mV  Width: 0.1 ms to 2.0 ms  Ascending time: 10 $\mu$ s to 100 $\mu$ s
Pulse Rejection	Pulse is rejected if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.13 are met:  Amplitude: $\pm 2$ mV to $\pm 700$ mV  Width: 0.1 ms to 2.0 ms  Ascending time: 10 $\mu$ s to 100 $\mu$ s
Pace pulse detecting lead: one among I, II, III, aVR, aVL, aVF, V1 to V6	
Minimum input slew rate (lead II)	> 2.5 V/S
☆Baseline Reset Time	< 3 s
Heart Rate	
HR Calculation	
☆Range	ADU: 15 bpm to 300 bpm  PED/NEO: 15 bpm to 350 bpm
☆Accuracy	$\pm 1\%$ or 1 bpm, whichever is greater
Resolution	1 bpm
Sensitivity	$\geq 300 \mu$ VPP
☆QRS Detection Range	The detection range has exceeded the requirement described in the standard:  Width: 70 ms~120 ms for adult, 40 ms~120 ms for Pediatric/neonate.  Amplitude: 0.5 mv~5 mv  In adult mode, these two signals are not responded: 1. when QRS amplitude of 0.15 mV or less is applied; 2. when QRS duration of 10 ms and QRS amplitude of 1 mV or less is applied.  Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.15.

PVC	
Range	ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min
Resolution	1 PVCs/min
Pause/min	
Range	ADU/PED/NEO: (0 to 30) pauses/min
Resolution	1 pause/min
ST value	
Range	-2.0 mV to +2.0 mV
Accuracy	-0.8 mV to +0.8 mV: $\pm 0.02$ mV or 10%, whichever is greater. Beyond this range: not specified.
Resolution	0.01 mV
HR Averaging Method	
Method 1	Heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals.
Method 2	If each of three consecutive RR intervals is greater than 1200ms, then the four most recent RR intervals are averaged to compute the HR.
Range of Sinus and SV Rhythm	
Tachy	Adult: RR interval for 5 consecutive QRS complex $\leq 0.5$ s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\leq 0.375$ s.
Normal	Adult: $0.5$ s $<$ RR interval for 5 consecutive QRS complex $< 1.5$ s. Pediatric/neonatal: $0.375$ s $<$ RR interval for 5 consecutive QRS complex $< 1$ s.
Brady	Adult: RR interval for 5 consecutive QRS complex $\geq 1.5$ s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\geq 1$ s.
Range of Ventricular Rhythm	
V-Tach	5 consecutive ventricular beats and ventricular HR $\geq 100$ bpm.

Vent Rhythm	Basic: 5 consecutive ventricular beats, and $40 \text{ bpm} \leq \text{ventricular HR} < 100 \text{ bpm}$ . Advanced: 5 consecutive ventricular beats, and $20 \text{ bpm} \leq \text{ventricular HR} < 40 \text{ bpm}$ .
Vent Brady	Basic: 5 consecutive ventricular beats, and ventricular HR $< 40 \text{ bpm}$ . Advanced: 5 consecutive ventricular beats, and ventricular HR $< 20 \text{ bpm}$ .
Maximum start-up alarm time for Tachycardia	
V-Tach  1 mV 206bpm	Gain 1.0: 10 s  Gain 0.5: 10 s  Gain 2.0: 10 s
V-Tach  2 mV 195bpm	Gain 1.0: 10 s  Gain 0.5: 10 s  Gain 2.0: 10 s
Response time of HeartRate Meter to Change in HR	HR range: 80 bpm to 120 bpm  Range : Within 11 s  HR range: 80 bpm ~ 40 bpm  Range : Within 11 s
☆Tall T-wave Rejection	Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.17 minimum recommended 1.2 mV T-Wave amplitude
Accuracy of Heart Rate Meter and Response to Irregular Rhythm	Complied with IEC 60601-2-27: 2011, Sect. 201.7.9.2.9.101 b) 4), the HR value after 20 seconds of stabilization is displayed as follows:  Ventricular bigeminy: $80 \text{ bpm} \pm 1 \text{ bpm}$ Slow alternating ventricular bigeminy: $60 \text{ bpm} \pm 1 \text{ bpm}$ Rapid alternating ventricular bigeminy: $120 \text{ bpm} \pm 1 \text{ bpm}$ Bidirectional systoles: $91 \text{ bpm} \pm 1 \text{ bpm}$
Time to Alarm for Heart Rate alarm conditions	Asystole alarm: $\leq 10 \text{ s}$  HR low alarm: $\leq 10 \text{ s}$  HR high alarm: $\leq 10 \text{ s}$

Arrhythmia analyses	Asystole	V-Fib/V-Tach	Couplet
	Vent Rhythm	PVC Bigeminy	PVC Trigeminy
	Tachy	R on T	PVC
	Irr Rhythm	Brady	Missed Beat
	Pacer not Pacing	Vent Brady	Pacer not Capture
	VEB	Run PVCs	Acc. Vent Rhythm
	IPVC	Non-Sustain VT	Multiform PVCs
	Pauses/min High	Pause	Afib
	PAC Bigeminy	PVCs High	Low Voltage(Limb)
	ExtremeBrady	PAC Trigeminy	Wide QRS Tachy
	Sustain VT	ExtremeTachy	V-Tach
12-lead ECG Synchronization Analysis	Average parameters of heart beat		
	Heart rate (bpm)		
	Time limit of P wave (ms)		
	PR interval (ms)		
	QRS interval (ms)		
	QT/QTC (ms)		
	P-QRS-T AXIS		

## A.12 RESP

Method	Impedance between RA-LL, RA-LA
Measurement lead	Options are lead I and II. The default is lead II.
Calculation Type	Manual, Automatic
Respiration excitation waveform	Sinusoid, 45.6 kHz ( $\pm 10\%$ ), $< 500 \mu\text{A}$
Measuring Sensitivity	Within baseline impedance range: $0.3 \Omega$
Waveform bandwidth	0.2 Hz to 2.5 Hz (-3 dB)
Baseline Impedance Range	$200 \Omega$ to $2500 \Omega$ (leads cables $1 \text{ K}\Omega$ resistance)
☆RR Measuring Range	

☆Adult	0 rpm to 120 rpm
☆Neo/Ped	0 rpm to 150 rpm
Resolution	1 rpm
☆Accuracy	
☆Adult	6 rpm to 120 rpm: 2 rpm 0 rpm to 5 rpm: not specified
☆Neo/Ped	6 rpm to 150 rpm: 2 rpm 0 rpm to 5 rpm: not specified
☆Gain Selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s
☆Apnea Alarm Time Setup	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.

## A.13 NIBP

Complies with IEC 80601-2-30: 2009+A1: 2013.

### ELITECH Module

Technique	Oscillometry
Mode	Manual, Auto, Continuous, Sequence
Measuring interval in AUTO Mode(unit: minute)	1/2/3/4/5/10/15/30/60/90/120/180/240/360/480 and User Define (default is 2.5)
Continuous	5 min, interval is 5 s
Measuring Parameter	SYS, DIA, MAP, PR
Pressure Unit	kPa, mmHg, cmH <sub>2</sub> O
☆Measuring Range (Applicable for CE registration area)	
☆Adult Mode	SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg
☆Pediatric Mode	SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg
☆Neonatal Mode	SYS: 25 mmHg to 140 mmHg DIA: 10 mmHg to 115 mmHg MAP: 15 mmHg to 125 mmHg

☆Measuring Range (Applicable for FDA registration area)	
☆Adult Mode	SYS: 40 mmHg ~ 270 mmHg DIA: 10 mmHg ~ 215 mmHg MAP: 20 mmHg ~ 235 mmHg
☆Pediatric Mode	SYS: 40 mmHg ~ 230 mmHg DIA: 10 mmHg ~ 180 mmHg MAP: 20 mmHg ~ 195 mmHg
☆Neonatal Mode	SYS: 40 mmHg ~ 135 mmHg DIA: 10 mmHg ~ 100 mmHg MAP: 20 mmHg ~ 110 mmHg
☆Alarm Type	SYS, DIA, MAP
☆ Cuff Pressure Measuring Range	0 mmHg ~ 300 mmHg
Pressure Resolution	1 mmHg
☆Maximum Mean Error	±5 mmHg
☆Maximum Standard Deviation	8 mmHg
Maximum measuring period	
Adult/Pediatric	120 s
Neonate	90 s
Typical Measuring Period	20 s to 35 s (depend on HR/motion disturbance)
Dual Independent Channel Overpressure Protection	
Adult	(297±3) mmHg
Pediatric	(245±3) mmHg
Neonatal	(147±3) mmHg
Pre-inflation Pressure	
Adult Mode	80 mmHg, 100 mmHg, 120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 220 mmHg, 240 mmHg Default: 160 mmHg
Pediatric Mode	80 mmHg, 100 mmHg, 120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg Default: 140 mmHg
Neonatal Mode	60 mmHg, 70 mmHg, 80 mmHg, 100 mmHg, 120 mmHg Default: 100 mmHg

Venipuncture pressure	
Adult	Default: 60 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg, 90 mmHg, 100 mmHg, 110 mmHg, 120 mmHg
Pediatric	Default: 40 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg
Neonatal	Default: 30 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg

**SunTech Module**

Method	Oscillometric
Mode	Manual, Auto, Continuous and Sequence
Measuring Interval in AUTO Mode (unit: minute)	1/2/3/4/5/10/15/30/60/90/120/240 and User Define
☆Measuring Parameter	SYS, DIA, MAP, PR
☆Measuring Range	
☆Adult Mode	SYS: 40 mmHg ~ 260 mmHg DIA: 20 mmHg ~ 200 mmHg MAP: 26 mmHg ~ 220 mmHg
☆Pediatric Mode	SYS: 40 mmHg ~ 230 mmHg DIA: 20 mmHg ~ 160 mmHg MAP: 26 mmHg ~ 183 mmHg
☆Neonatal Mode	SYS: 40 mmHg ~ 130 mmHg DIA: 20 mmHg ~ 100 mmHg MAP: 26 mmHg ~ 110 mmHg
☆Alarm Type	SYS, DIA, MAP
Pressure Resolution	1 mmHg
☆Maximum mean error	±5 mmHg
☆Maximum standard deviation	8 mmHg
Maximum measuring period	
Adult	130 s

Adult (Sports Mode)	120 s
Pediatric	90 s
Neonate	75 s
Overpressure protection	
Adult/Pediatric	< 300 mmHg
Neonate	< 150 mmHg
Pre-inflation Pressure	
Adult Mode	120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 220 mmHg, 240 mmHg, 260 mmHg, 280 mmHg Default: 160 mmHg
Pediatric Mode	80 mmHg, 100 mmHg, 120 mmHg, 140 mmHg, 150 mmHg, 160 mmHg, 180 mmHg, 200 mmHg, 220 mmHg, 250 mmHg Default: 140 mmHg
Neonatal Mode	60 mmHg, 70 mmHg, 80 mmHg, 90 mmHg, 100 mmHg, 120 mmHg, 140 mmHg Default: 90 mmHg

## A.14 SpO<sub>2</sub>

Complies with ISO 80601-2-61: 2011.

### ELITECH Module

Measuring Range	0% to 100%
Alarm Range	20% to 100%
Resolution	1%
☆Data Update Period	1 s
☆Accuracy	
☆Adult /Pediatric	±2% (70% to 100% SpO <sub>2</sub> )
	Undefined (0% to 69% SpO <sub>2</sub> )
☆Neonate	±3% (70% to 100% SpO <sub>2</sub> )
	Undefined (0% to 69% SpO <sub>2</sub> )
Sensor	
Red light	(660±3) nm
Infrared light	(905±10) nm

Emitted light energy	< 15 mW
PI	
Measuring Range	0-10, invalid PI value is 0.
Resolution	1

**Nellcor Module**

Measuring Range	1% to 100%	
Alarm Range	20% to 100%	
Resolution	1%	
☆ Data Update Period	1 s	
☆Accuracy	DS-100A, OXI-A/N(Adult) D-YS (Adult and Pediatric) OXI-P/I (Pediatric)	± 3% (70% to 100% SpO <sub>2</sub> )
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	±2% (70% ~ 100% SpO <sub>2</sub> )
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	±3% (60% ~ 80% SpO <sub>2</sub> )
	If sensor is used for neonate as recommended, the accuracy will be larger greater than adult by ±1.	
Sensor	Wave length: approximately 660 nm and 900 nm	
	Emitted light energy: < 15 mW	

**NOTE:**

Information about the wave length range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

**A.15 PR**

		Measuring range	Accuracy	Resolution
PR (SpO <sub>2</sub> )	ELITECH	25 bpm to 300 bpm	±2 bpm	1 bpm
	Nellcor	20 bpm to 300 bpm	± 3 bpm (20 bpm to 250 bpm)	1 bpm

		Measuring range	Accuracy	Resolution
PR (NIBP)	ELITECH	40 bpm to 240 bpm	±3 bpm or 3.5%, whichever is greater	1 bpm
	SunTech	30 bpm to 220 bpm	±3 bpm or ±2%, whichever is greater	1 bpm
PR (IBP)	ELITECH	20 bpm to 300 bpm	30 bpm to 300 bpm: ±2 bpm or ±2%, whichever is greater; 20 bpm to 29 bpm: undefined	1 bpm

## A.16 TEMP

Complies with ISO 80601-2-56: 2009.

Channel	2
Sensor type	YSI-10K and YSI-2.252K
Technique	Thermal resistance
Measuring Mode	Direct Mode
Position	Skin, oral cavity, rectum
Measuring Range	0 °C to 50 °C(32 °F to 122 °F)
Resolution	0.1 °C (0.1 °F)
☆Accuracy <sup>1</sup>	±0.3 °C
Refresh Time	Every 1 s to 2 s
Temperature Calibration	At an interval of 5 minutes to 10 minutes
Transient Response Time	≤ 30 s

Note 1: The accuracy consists of two parts, as following:

- Accuracy (not including sensor): ± 0.1 °C
- Sensor accuracy: ≤ ±0.2 °C

## A.17 IBP

Complies with IEC 60601-2-34: 2011.

Technique	Direct invasive measurement
☆Measuring Range	
Art	0 mmHg to + 300 mmHg

PA	-6 mmHg to + 120 mmHg
CVP/RAP/LAP/ICP	-10 mmHg to + 40 mmHg
P1/P2	-50 mmHg to + 300 mmHg
Resolution	1 mmHg
☆Accuracy (not including sensor)	± 2% or ±1 mmHg, whichever is greater ICP: 0 mmHg to 40 mmHg: ±2% or ±1 mmHg, whichever is greater; -10 mmHg to -1 mmHg: undefined
Pressure Unit	kPa, mmHg, cmH <sub>2</sub> O
Pressure sensor	
Sensitivity	5 ( $\mu$ V/V/mmHg)
Impedance	(300 to 3000) $\Omega$
Filter	DC~12.5 Hz; DC~40 Hz
Zero	Range: ±200 mmHg
Pressure Calibration Range	IBP (excluding ICP) 80 mmHg to 300 mmHg
	ICP 10 mmHg to 40 mmHg
Volume displacement of MSI	7.4 x 10 <sup>4</sup> mm <sup>3</sup> /100mmHg

## A.18 CO<sub>2</sub>

Complies with ISO 80601-2-55: 2011.

Applicable Patient Type	Adult, pediatric and neonatal patients	
Technique	Infra-red Absorption Technique	
Unit	mmHg, %, Kpa	
☆Measuring Range		
☆EtCO <sub>2</sub>	0 mmHg ~ 150 mmHg	
☆FiCO <sub>2</sub>	3 mmHg ~ 50 mmHg	
☆AwRR	2 rpm ~ 150 rpm (Sidestream)	
Resolution	EtCO <sub>2</sub>	1 mmHg
	FiCO <sub>2</sub>	1 mmHg
	AwRR	1 rpm

☆EtCO <sub>2</sub> Accuracy	±2 mmHg, (0 to 40) mmHg
	±5% of reading, (41 to 70) mmHg
	±8% of reading, (71 to 100) mmHg
	±10% of reading, (101 to 150) mmHg
	±12% of reading, RR is over 80 rpm (sidestream)
☆AwRR Accuracy	±1 rpm
Operation Mode	Measure, standby
Sample Gas Flowrate (sidestream)	(50 ±10) ml/min
O <sub>2</sub> Compensation	
Range	0%~ 100%
Resolution	1%
Default	16%
Barometric pressure compensation	User setup
Anesthetic Gas Compensation	
Range	0% ~ 20%
Resolution	0.1%
Default	0.0%
Balance Gas Compensation	Room air, N <sub>2</sub> O, helium
Stability	
Short Term Drift	Drift over 4 hours < 0.8 mmHg
Long Term Drift	120 hours
Total System Response Time	4.7 s
Alarm Type	EtCO <sub>2</sub> , FiCO <sub>2</sub> , AwRR
Apnea Alarm Delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.
Data Sample Rate	100 Hz
Sensor Response Time (sidestream)	< 3 seconds, including transport time and rise time

Interfering Gas and Vapor Affects on EtCO<sub>2</sub> Measurement Values:

Gas or vapor	Gas level (%)	Quantitative effect/Comments
--------------	---------------	------------------------------

Nitrous oxide	60	Dry and Saturated Gas
Halothane	4	(0 ~ 40) mmHg: $\pm 1$ mmHg additional error
Enflurane	5	(41 ~ 70) mmHg: $\pm 2.5\%$ additional error
Isoflurane	5	(71 ~ 100) mmHg: $\pm 4\%$ additional error
Sevoflurane	5	(101 ~ 150) mmHg: $\pm 5\%$ additional error
Xenon	80	*Additional worst case error when compensation for P <sub>B</sub> , O <sub>2</sub> , N <sub>2</sub> O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.
Helium	50	
Desflurane	15	Desflurane:  The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38 mmHg.  Xenon:  The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38 mmHg.

Barometric Pressure on EtCO<sub>2</sub> Measurement Values:

Quantitative effect
Ambient Barometric, Operational
(0 ~ 40) mmHg: $\pm 1$ mmHg additional error
(41 ~ 70) mmHg: $\pm 2.5\%$ additional error
(71 ~ 100) mmHg: $\pm 4\%$ additional error
(101 ~ 150) mmHg: $\pm 5\%$ additional error
*Additional worst case error when compensation for P <sub>B</sub> , O <sub>2</sub> , N <sub>2</sub> O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.

#### NOTE:

Respiration Rate accuracy was verified by using a solenoid test setup to deliver a square wave of known CO<sub>2</sub> concentration to the device. 5% and 10% CO<sub>2</sub> concentrations were used. Respiration rate was varied over the range of the device. Pass/Fail criteria was comparison of the respiratory rate output from the sensor to the frequency of the square wave.

#### A.19 C.O.

Technique	Thermodilution Technique
Measure Parameters	C.O., TB, TI
Measuring Range	

C.O.	0.1 L/min to 20 L/min
TB	23 °C to 43 °C (73.4 °F to 109.4 °F)
TI	-1 °C to 27 °C (30.2 °F to 80.6 °F)
Resolution	
C.O.	0.1 L/min
TB, TI	0.1 °C (+0.1 °F)
Accuracy	
C.O.	± 5% or ± 0.2 L/min, whichever is greater
TB	± 0.1 °C (not including sensor)
TI	± 0.1 °C (not including sensor)

**NOTE:**

At least 90% of the C.O. data should reside inside the bounded region, and the lower 95% confidence interval should not exceed 85%.

**A.20 Wi-Fi**

IEEE	802.11b/g/n
Frequency	2.4 GHz ISM band
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS
Typical Transmit Power (±2 dBm)	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM

**A.21 Interface****A.21.1 USB Interface**

Number of USB Interfaces	Standard: 1
Drive Mode	OTG, USB1.0/2.0 protocol
Power Supply	5 VDC±5%, 150 mA Max.
Interface Type	Micro USB-type port

## B EMC Information

### - Guidance and Manufacture's Declaration

#### B.1 Electromagnetic Emissions

Guidance and manufacture's declaration – electromagnetic emission		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	PM PRO-2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	PM PRO-2 is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

#### B.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC/EN 61000-4-5	$\pm 1$ kV for line to line	$\pm 1$ kV for line to line	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50 Hz /60 Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % $U_T$ ; 0.5 cycle At $0^\circ$ , $45^\circ$ , $90^\circ$ , $135^\circ$ , $180^\circ$ , $225^\circ$ , $270^\circ$ and $315^\circ$  0 % $U_T$ ; 1 cycle and 70 % $U_T$ ; 25/30 cycles ) Single phase: at $0^\circ$  0 % $U_T$ ; 250/300 cycle	0 % $U_T$ ; 0.5 cycle At $0^\circ$ , $45^\circ$ , $90^\circ$ , $135^\circ$ , $180^\circ$ , $225^\circ$ , $270^\circ$ and $315^\circ$  0 % $U_T$ ; 1 cycle and 70 % $U_T$ ; 25/30 cycles ) Single phase: at $0^\circ$  0 % $U_T$ ; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of PM PRO-2 requires continued operation during power mains interruptions, it is recommended that PM PRO-2 be powered from an uninterruptible power supply or a battery.
Electrical transient conduction along supply lines (Only applicable to PS900Y)	As specified in ISO 7637-2	As specified in ISO 7637-2	For PM PRO-2 intended to be installed in passengercars and light commercial vehicles including ambulances fitted with 12 V electrical systems or commercial vehicles including ambulances fitted with 24 V electrical systems.

**NOTE**  $U_T$  is the a.c. mains voltage prior to application of the test level.

## B.3 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
PM PRO-2 is intended for use in the electromagnetic environment specified below. The customer or the user of PM PRO-2 should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC/EN 61000-4-6	3 V <sub>rms</sub> 150 kHz to 80 MHz 6Vrms <sup>c</sup> in ISM bands between 0.15 MHz and 80 MHz	3 V <sub>rms</sub> 150 kHz to 80 MHz 6Vrms <sup>c</sup> in ISM bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of PM PRO-2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b> $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC/EN 61000-4-3	20 V/m 80 MHz to 2.7 GHz	20 V/m 80 MHz to 2.7 GHz	$d = 0.18 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.35 \sqrt{P}$ 800 MHz to 2.7 GHz  $d = 6 \sqrt{P/E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer).  Where P is the maximum output power rating of the transmitter in
See Table 1		Comply with Table 1	

		<p>watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<b>NOTE 1</b> At 80 MHz and 800 MHz, the higher frequency range applies.		
<b>NOTE 2</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radiobroadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which PM PRO-2 is used exceeds the applicable RF compliance level above, PM PRO-2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating PM PRO-2.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> <p>c The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.</p>		

**Table 1 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment**

Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	Immunity test level (V/m)						
385	380-390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	1.8	0.3	27						
450	430-470	GMRS 460, FRS 460	FM <sup>c)</sup> $\pm 5$ kHz deviation 1 kHz sine	2	0.3	28						
710	704-787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9						
745												
780												
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18 Hz	2	0.3	28						
870												
930												
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28						
1845												
1970												
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0.3	28						
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9						
5500												
5785												
<b>NOTE</b> If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.												
a) For some services, only the uplink frequencies are included.												
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.												
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.												

## B.4 Recommended Separation Distances

<b>Recommended separation distances between portable and mobile RF communications equipment and PM PRO-2</b>			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	150 kHz to 80 MHz $d = \sqrt{1.2 P}$	80 MHz to 800 MHz $d = \sqrt{0.18 P}$	800 MHz to 2.7 GHz $d = \sqrt{0.35 P}$
0.01	<b>0.12</b>	<b>0.018</b>	<b>0.035</b>
0.1	<b>0.38</b>	<b>0.057</b>	<b>0.11</b>
1	<b>1.2</b>	<b>0.18</b>	<b>0.35</b>
10	<b>3.8</b>	<b>0.57</b>	<b>1.1</b>
100	<b>12</b>	<b>1.8</b>	<b>3.5</b>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## C Default Settings

This appendix documents the most important default settings of your monitor as it is delivered from the factory.

### NOTE:

If your monitor has been preconfigured according to your requirements, the settings at delivery will be different from the default settings listed here.

### C.1 Patient Information Default Settings

Patient Information Settings	
Patient Type	Adult
Pace	Off

### C.2 Alarm Default Settings

Alarm Settings	
Pause Time	120 s
Sensor Off Alarm	Off
Alarm Latch	Off

### C.3 ECG Default Settings

ECG Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	120	160	200
Alarm Low Limit	50	75	100
ARR Analysis ThresholdValue			
Low Voltage(Limb)	0.5 mV		
Pause	3 s		
Sustain VT	30 s		
PAC Bigeminy	8/min		

Pauses/min High	8/min		
PVCs High	10/min		
PAC Trigeminy	16/min		
ExtremeTachy	160	180	200
Extreme Brady	30	50	60
Pace	Off		
Electrode Type	5 Electrodes		
Screen Layout	Normal		
Filter	Monitor		
Smart Lead Off	Off		
Heart Volume	3		
ST Analysis	Off		
Alarm Switch	Off		
Alarm Level	Medium		
Alarm Record	Off		
Alarm High Limit (ST-X)	0.2		
Alarm Low Limit (ST-X)	-0.2		
QT Analysis	Off		
QTc	500	480	460
ΔQTc	60		
X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6.			
	ADU	PED	NEO
ARR Analysis	On	Off	Off
ARR Analysis	On		
ARR Alarm Settings	Alarm Switch	Alarm Level	Alarm Record
Asystole	On (non-adjustable)	High (non-adjustable)	Off
V-Fib/V-Tach	On	High (non-adjustable)	Off
R on T	On	Medium	Off
PVC	Off	Low	Off

Couplet	On	Low	Off
Run PVCs	On	Low	Off
PVC Bigeminy	On	Medium	Off
PVC Trigeminy	On	Low	Off
Tachy	On	Medium	Off
Brady	On	Medium	Off
Missed Beat	Off	Low	Off
Irr Rhythm	Off	Low	Off
Pacer not Capture	On	Medium	Off
Pacer not Pacing	On	Medium	Off
Vent Brady	On	High (non-adjustable)	Off
Vent Rhythm	On	Medium	Off
Sustain VT	On (non-adjustable)	High (non-adjustable)	Off
ExtremeTachy	On	High (non-adjustable)	Off
ExtremeBrady	On	High (non-adjustable)	Off
V-Tach	On	High (non-adjustable)	Off
Wide QRS Tachy	On	Medium	Off
Non-Sustain VT	On	Medium	Off
Afib	On	Medium	Off
Acc. Vent Rhythm	On	Low	Off
Pause	On	Medium	Off
Pauses/min High	On	Medium	Off
PVCs High	On	Medium	Off
VEB	Off	Low	Off
Multiform PVCs	Off	Low	Off
IPVC	Off	Low	Off
PAC Bigeminy	Off	Low	Off

PAC Trigeminy	Off	Low	Off
Low Voltage(Limb)	Off	Low	Off

#### C.4 RESP Default Settings

RESP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	30	30	100
Alarm Low Limit	8	8	30
Apnea Alarm Time	20 s		
Calculation Type	Auto		
Resp Type	II		
Sweep	12.5 mm/s		
Amplitude	1		

#### C.5 SpO<sub>2</sub> Default Settings

SpO <sub>2</sub> Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	100	100	95
Alarm Low Limit	90	90	88
Pitch Tone	On		
Sensitivity	Medium		
SatSeconds (Nellcor Module)	Off		
Sweep	12.5 mm/s		
SpO <sub>2</sub> Desat Limit	80%		

#### C.6 PR Default Settings

PR Settings	ADU	PED	NEO
PR Source	SpO <sub>2</sub>		

Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	120	160	200
Alarm Low Limit	50	75	100
Pulse Volume	3		
Alarm Source	Auto		

## C.7 NIBP Default Settings

NIBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (SYS)	160	120	90
Alarm Low Limit (SYS)	90	70	40
Alarm High Limit (Map)	110	90	70
Alarm Low Limit (Map)	60	50	30
Alarm High Limit (DIA)	90	70	60
Alarm Low Limit (DIA)	50	40	20
Venipuncture pressure	60	40	30
Inflation value	ELITECH Module	160	140
	SunTech Module	160	140
Unit	mmHg		
Interval	Manual		

## C.8 TEMP Default Settings

TEMP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (T1)	39.0	39.0	39.0
Alarm Low Limit (T1)	36.0	36.0	36.0

Alarm High Limit (T2)	39.0	39.0	39.0
Alarm Low Limit (T2)	36.0	36.0	36.0
Alarm High Limit (TD)	2.0	2.0	2.0
Unit	°C		

## C.9 IBP Default Settings

IBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Unit	mmHg		
Filter	12.5Hz		
	SYS, DIA, MAP	SYS, DIA, MAP	SYS, DIA, MAP
Alarm High Limit (ART, P1, P2)	160, 90, 110	120, 70, 90	90, 60, 70
Alarm Low Limit (ART, P1, P2)	90, 50, 70	70, 40, 50	55, 20, 35
Alarm High Limit (PA)	35, 16, 20	60, 4, 26	60, 4, 26
Alarm Low Limit (PA)	10, 0, 0	24, -4, 12	24, -4, 12
	MAP	MAP	MAP
Alarm High Limit (CVP, RAP, LAP, ICP)	10	4	4
Alarm Low Limit (CVP, RAP, LAP, ICP)	0	0	0

## C.10 CO<sub>2</sub> Default Settings

CO <sub>2</sub> Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Work Mode	Standby		
Unit	mmHg		
Apnea Time	20 s		
O <sub>2</sub> Compensate	16%		

Anes Agent	0%		
Alarm High Limit (EtCO <sub>2</sub> )	50	50	45
Alarm Low Limit (EtCO <sub>2</sub> )	25	25	30
Alarm High Limit (FiCO <sub>2</sub> )	4	4	4
Alarm High Limit (AwRR)	30	30	100
Alarm Low Limit (AwRR)	8	8	30
Sweep	6.25 mm/s		
Amplitude	Low		

## C.11 C.O. Default Settings

C.O. Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (TB)	40	40	40
Alarm Low Limit (TB)	30	30	30
Injective Temperature Source	Auto		
Temperature Unit	°C		
Interval	30		
Constant	0.542		

## D Abbreviation

Abbr	English Full Name/Description
AC	Alternating Current
Acc. Vent Rhythm	Accelerated Idioventricular Rhythm
Adu	Adult
Afib	Atrial Fibrillation
Art	Arterial
aVF	Left Foot Augmented Lead
aVL	Left Arm Augmented Lead
aVR	Right Arm Augmented Lead
AwRR	Airway Respiration Rate
BC	Burst Count
BP	Blood Pressure
Brady	Bradycardia
CISPR	International Special Committee on Radio Interference
CMS	Central Monitoring System
C.O.	Cardiac output
CO <sub>2</sub>	Carbon Dioxide
Couplet	Ventricular Couplets
CVP	Central Venous Pressure
DC	Direct Current
DDoS	Distributed Denial of Service
Dia	Diastolic
DoS	Denial of Service
ECG	Electrocardiogram
EEC	European Economic Community
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
ESU	Electrosurgical Unit
EtCO <sub>2</sub>	End-tidal Carbon Dioxide
ExtremeTachy	Extreme Tachycardia
ExtremeBrady	Extreme Bradycardia
FCC	Federal Communication Commission
FiCO <sub>2</sub>	Fraction of Inspired Carbon Dioxide

Abbr	English Full Name/Description
HR	Heart Rate
IBP	Invasive Blood Pressure
ICP	Intracranial Pressure
ICU	Intensive Care Unit
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
IPVC	Inserted Premature Ventricular Contraction
Irr Rhythm	Irregular Rhythm
LA	Left Arm
LAP	Left Atrial Pressure
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LL	Left Leg
Low Voltage(Limb)	Low QRS Voltage
MAP	Mean Arterial Pressure
MDD	Medical Device Directive
MRI	Magnetic Resonance Imaging
Multiform PVCs	Multiformed Premature Ventricular Contractions
N/A	Not Applied
N <sub>2</sub>	Nitrogen
N <sub>2</sub> O	Nitrous Oxide
Neo	Neonate
NIBP	Non-invasive Blood Pressure
Non-Sustain VT	Nonsustained Ventricular Tachycardia
O <sub>2</sub>	Oxygen
OxyCRG	Oxygen Cardio-respirogram
PA	Pulmonary Artery
PAC Bigeminy	Premature Atrial Contraction (PAC) Bigeminy
PAC Trigeminy	Premature Atrial Contraction (PAC) Trigeminy
PAWP	Pulmonary Artery Wedge Pressure
Ped	Pediatric
PI	Perfusion Index

Abbr	English Full Name/Description
Pleth	Plethysmogram
PR	Pulse Rate
PVC	Premature Ventricular Contraction
PVC Bigeminy	Premature Ventricular Contraction Bigeminy
PVC Trigeminy	Premature Ventricular Contraction Trigeminy
R	Right
RA	Right Arm
RAP	Right Atrial Pressure
Resp	Respiration
RL	Right Leg
RR	Respiration Rate
Run PVCs	Run premature Ventricular Contractions
SpO <sub>2</sub>	Pulse Oxygen Saturation
SR	Suppression Ratio
SYS	Systolic Pressure
Sustain VT	Sustained Ventricular Tachycardia
Tachy	Tachycardia
TB	Blood Temperature
TD	Temperature Difference
TEMP	Temperature
USB	Universal Serial Buss
VEB	Ventricular Escape Beat
Vent Brady	Ventricular Bradycardia
Vent Rhythm	Ventricular Rhythm
V-Fib/V-Tach	Ventricular Fibrillation/Ventricular Tachycardia
V-Tach	Ventricular Tachycardia
Wide QRS Tachy	Wide QRS Tachycardia



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